POMERANTZ LLP
Josh Silverman (*pro hac vice*)
Louis C. Ludwig
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jpsilverman@pomlaw.com
lcludwig@pomlaw.com

ROCHE FREEDMAN LLP
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
Constantine P. Economides (*pro hac vice* forthcoming)
1 SE 3rd Ave., Suite 1250
Miami, Florida 33131
Telephone: (305) 971-5943
ingo@rochefreedman.com
vel@rochefreedman.com
ceconomides@rochefreedman.com

Counsel for Lead Plaintiff and the Class

- additional counsel on signature page -

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE CORMEDIX INC. SECURITIES LITIGATION	Case No. 2:21-cv-14020 JXN CLW **CLASS ACTION**
THIS DOCUMENT RELATES TO: ALL CASES	CONSOLIDATED AMENDED CLASS ACTION COMPLAINT Honorable Julien Neals **JURY TRIAL DEMANDED**

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Lead Plaintiff John V. Levon ("Plaintiff"), by and through his undersigned attorneys, on behalf of himself and all others similarly situated, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the CorMedix Inc.'s ("CorMedix" or the "Company") public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding CorMedix, analysts' reports and advisories about CorMedix, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of two proposed classes (the "Classes"):

a) All persons who purchased CorMedix securities pursuant or traceable to: (i) the Company's November 27, 2020 "At the Market" ("ATM") offering (the "Offering") pursuant to CorMedix's Form S-3 Registration Statement and its Prospectus Supplement, dated November 27, 2020 (together, the "Offering Documents"). This class asserts claims only for violations of §§ 11 and 15 of the Securities Act of 1933 (the "1933 Act"), 15 U.S.C. §§ 77k and 77o (the "1933 Act Class"); and

b) All persons and entities, other than Defendants, that purchased or otherwise acquired CorMedix securities between October 16, 2019 and

September 6, 2021, inclusive (the "Class Period"). This class asserts claims only for violations of §§ 10(b) and 20(a) of the Securities Act of 1934 (the "1934 Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.1 b-5 (the "1934 Act Class").

2. For the last decade, CorMedix has primarily focused on developing its lead product candidate, Neutrolin® ("Neutrolin"), a purportedly novel antibacterial and antifungal solution designed to prevent costly and dangerous catheter-related bloodstream infections ("CRBSIs") and thrombosis in patients requiring central venous catheters in clinical settings such as hemodialysis, critical/intensive care, and oncology—a catheter lock solution ("CLS").

3. CorMedix received CE-Mark approval for Neutrolin in July 2013 and a label expansion in September 2014 in the European Union (EU) and in December 2014 in Germany. In April 2017, Hemotech SAS ("Hemotech") became the Company's marketing partner in France and certain overseas territories and launched Neutrolin in those regions. CorMedix had been selling Neutrolin commercially in Germany since December 2013, but with Hemotech, was able to expand to Middle Eastern and other EU countries. CorMedix has always manufactured Neutrolin through third-party commercial manufacturing organizations ("CMOs").

4. Simultaneously, in late 2013, CorMedix began actively pursuing U.S. approval of Neutrolin by meeting with the U.S. Food and Drug Administration

("FDA").[1] Despite the CorMedix Defendants' assurances during the Class Period about their past successful manufacturing and regulatory experience and of the FDA's support for the Company's manufacturing program, CorMedix has still not resubmitted its Neutrolin NDA with the requisite manufacturing information as of the filing of this complaint.[2]

5. Drug sponsors seeking FDA approval of a new drug for U.S. sale, marketing, and commercial distribution must submit a New Drug Application ("NDA"). Through the NDA process, the FDA is given information to determine whether: (i) a drug is effective and safe in its proposed use(s), and its benefits outweigh its risks; (ii) the drug's proposed labeling is appropriate, and what it should contain; and (iii) the methods used to manufacture the drug and the controls used to maintain its quality are adequate to preserve its identity, strength, quality and purity.[3]

[1] The FDA was created *via* the Food, Drug and Cosmetic Act ("FDCA") to "protect the public health" by ensuring that "drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [this section] is effective with respect to such drug." 21 U.S.C. § 355(a).

[2] The "CorMedix Defendants" are the Company, Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, and Jack Armstrong. *See also* ¶¶40-47 below.

[3] U.S. FOOD & DRUG ADMIN., *New Drug Application (NDA)* (June 10, 2019), https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

6. As part of an NDA, clinical trials must be successfully conducted.[4] If questions or difficulties related to trial data arise, the FDA has the discretion to convene an advisory committee.[5]

7. In addition, an NDA must successfully demonstrate Chemistry, Manufacturing and Controls ("CMC") to ensure that the drug is consistently effective, safe, and high quality. CMC encompasses the entire product lifecycle – from Phase I clinical trials through post-approval and beyond – in order to sustain a connection between the investigational drug used in clinical studies and the commercial drug marketed and available to consumers. CMC applies to the drug itself ***and*** the facility in which the drug is manufactured.

8. Approximately six months prior to the planned NDA submission date, the FDA's CMC review team will meet with the drug sponsor to discuss potential issues to ensure the submission of a complete NDA.[6] CMC issues that may arise in

[4] U.S. FOOD & DRUG ADMIN., *What Are the Different Types of Clinical Research?* (Jan. 4, 2018), https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research.

[5] U.S. FOOD & DRUG ADMIN., *Learn About FDA Advisory Committees* (Oct. 19, 2020), https://www.fda.gov/patients/about-office-patient-affairs/learn-about-fda-advisory-committees.

[6] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Guidance for Industry – IND Meetings for Human Drugs and Biologics* (May 2001), https://www.fda.gov/files/Guidance-for-Industry---IND-Meetings-for-Human-Drugs-and-Biologics---Chemistry--Manufacturing--and-Controls-Information-%28PDF%29.pdf.

this meeting include: (i) the relationship between the manufacturing, formulation, and packaging of the drug used in Phase III studies and the drug intended for marketing, and whether any previously agreed upon comparability or bridging studies have been completed; (ii) whether the NDA will contain adequate stability data in accordance with stability protocols previously agreed upon with the FDA; (iii) whether all facilities (*e.g.*, manufacturing, testing, packaging) will be ready for inspection by the time of the NDA submission; and (iv) any other issues, potential problems, or regulatory issues raised by the FDA or sponsor.

9. Before the Class Period began, CorMedix appeared to be on the way to successfully developing Neutrolin. The Company had received FDA approval to initiate a Phase 3 clinical trial (LOCK-IT-100) in October 2014,[7] which had launched in December 2015, and by July 2019, had yielded sufficient data to support the NDA for Neutrolin without the need for a second clinical trial.[8] The Company was also able to get Neutrolin designated as a Qualified Infectious Disease Product ("QIDP") and approved for the FDA's Fast Track in January 2015.[9]

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[7] *CorMedix Receives Approval From FDA to Initiate a Clinical Trial for Neutrolin in the US*, YAHOO!FINANCE (Oct. 27, 2014), https://finance.yahoo.com/news/cormedix-receives-approval-fda-initiate-125029532.html.

[8] *Cormedix Receives Encouraging FDA Feedback On Neutrolin® Lock-It-100 Data*, CORMEDIX, INC. (July 9, 2019), https://www.cormedix.com/cormedix-receives-encouraging-fda-feedback-neutrolin-lock-100-data/.

[9] QDIP provides five years of marketing exclusivity on top of the five years

10. After completing its clinical trials, CorMedix began to focus on ensuring its commercial manufacturing met FDA standards – making it clear to investors that the Company knew what it was doing in that regard. In August 2019, Defendant Armstrong, the Company's Executive Vice President (EVP) of Technical Operations since 2017, specifically assured investors that:

> CorMedix has been manufacturing and selling Neutrolin outside the U.S. for the last five years. We have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at three different manufacturing sites. This should give you comfort that we understand Neutrolin's manufacturing, technical, analytical processes as well as the quality controls and the systems that go with it. … And importantly, ***the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved***.[10]

11. Thus, on the first day of the Class Period, October 16, 2019, CorMedix seemed to have all the necessary information – including the manufacturing information – needed to submit an NDA for Neutrolin, when it issued a press release announcing a "Successful CMC Interaction with the FDA[.]" The Company claimed that "[t]he FDA was supportive of Neutrolin's proposed manufacturing program,

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granted upon NDA approval; Fast Track facilitates the development of drugs intended to address an unmet medical need and provides eligibility for priority review of the marketing application. *See* U.S. FOOD & DRUG ADMIN., *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review* (Feb. 23, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review.

[10] The "CorMedix Defendants" are the Company, Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, and Jack Armstrong. *See also* ¶¶40-47 below.

including the active pharmaceutical ingredients (API), the container closure and testing," and "[n]o further CMC meetings with FDA [we]re planned prior to NDA submission." On this announcement, CorMedix's stock price increased over 9%.

12. Then, during the first earnings call of the Class Period, on November 14, 2019, while reiterating that "[a]s our press release of 16 October indicated[,] the outcome of our interaction with the FDA was very positive[,]" the "FDA was supportive of the core manufacturing processes for the drug product," and "[n]o further CMC meetings with FDR are planned prior to the NDA submission," Defendant Armstrong noted that that "FDA did request some additional data which we are working to complete." Armstrong, however, did not elaborate on the specific nature of the requested "additional data."

13. While hinting at a possible issue in CorMedix's CMC module for Neutrolin that concerned the FDA enough to request more information, Armstrong quickly went on to assure investors of the Company and its manufacturing team's proven experience and competence, stating, in relevant part:

> ***CorMedix has been manufacturing and selling Neutrolin outside the US for the last five years. We've successfully carried out technical transfer and validation of the manufacturing process which is (sic) enable the successful production of product at three different manufacturing sites.*** As mentioned previously, I have working with me a very experienced and competent team, they have the needed breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance that is necessary for both the US and foreign markets.

14. As the market absorbed these and other positive statements about how the Company was on track for a successful NDA submission, its stock jumped 24% over the next two trading days.

15. After the FDA accepted the Neutrolin NDA for rolling review in February 2020, CorMedix began its modular submission the following month, and completing it in June 2020. At the same time, the FDA begun to substantively review the NDA and have an ongoing dialogue with the Company to assist it in determining, among other things, whether Neutrolin was safe and effective for its intended use and whether the facility in which it was to be manufactured, processed, packaged, or held met standards designed to assure its continued safety, quality, and purity.

16. By May 2020, the FDA had conditionally approved DefenCath™ ("DefenCath") as the U.S. proprietary name for Neutrolin. In the same month, the Company formed its wholly owned subsidiary in Spain, CorMedix Spain, S.L.U., to be close to, and to better oversee and/or manage, its CMO for its U.S. drug product as the COVID-19 pandemic spread throughout the globe.

17. In the face of the ongoing pandemic, on July 8, 2020, the CorMedix Defendants highlighted their ability to submit a complete NDA – via their third-party CMO – to investors despite challenges caused by the pandemic. In so doing, they portrayed the Company and its CMO as having successfully collected all the information and/or data required to meet regulatory standards: all that was left was

FDA approval. On this news, CorMedix's stock price increased 7%.

18. Throughout the rest of the Class Period, the CorMedix Defendants touted more milestones that maintained or increased the Company's stock price while regularly noting that the FDA "had not identified any potential review issues":

- 8/31/20: CorMedix announced that the FDA had accepted the DefenCath NDA for filing and granted it Priority Review[11] with a Prescription Drug User Fee Act ("PDUFA") date of February 28, 2021.
- 11/18/20: CorMedix announced that an advisory committee meeting for the DefenCath NDA was not needed.

19. Capitalizing on its stock price, Cormedix conducted a public offering on July 29, 2020 and an ATM offering on November 27, 2020 ("Offering").

20. Unbeknownst to investors, however, the CorMedix Defendants had submitted the DefenCath NDA without first competently verifying its completeness – despite publicly representing otherwise. Based on well-established regulatory standards and the Company's ongoing dialogue with the FDA, the CorMedix Defendants were well aware of all the information and/or data that had to be provided to the FDA during the NDA process in order to prevent a Complete Response Letter ("CRL") and any delays in the approval process. Nevertheless, by submitting the DefenCath NDA without warning investors about any possible

[11] Under Priority Review, the FDA reduced its review time from ten months to six. *See* U.S. FOOD & DRUG ADMIN., *Priority Review* (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.

manufacturing issues, and then conducting the Offering, Defendants benefited from the highly inflated share price caused by the CorMedix Defendants' misrepresentations and omissions of material facts concerning the sufficiency of the NDA and manufacturing capabilities of the Company's CMO.

21. Investors were thus shocked when, on March 1, 2021, CorMedix issued a press release (the "3/1/2021 Press Release) announcing a CRL instead of FDA approval. The Company detailed that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility"; the "FDA did not specify the issues and CorMedix intends to work with the manufacturing facility to develop a plan for resolution when FDA informs the facility of the specific concerns"; and the "FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications."

22. On this news, CorMedix's stock price fell nearly 40% on March 1, 2021. As one industry analyst explained, the "CRL due to third party manufacturing issues … ***comes as a surprise as the product has already been in production and commercial in the EU, albeit at limited capacity.***" (Emphasis in original).

23. While conceding their knowledge of the FDA's request for more information from their CMO, the CorMedix Defendants assured industry analysts

(and investors) that "the CMO manufactures drugs sold in the U.S.[,] implying some level of FDA inspection in the past that passed FDA's standards" and "the CMO is experienced in handling drug/device combos similar in scope to Defencath."

24. Then, during the Company's first call with analysts and investors after the CRL on March 9, 2021, the CorMedix Defendants downplayed the issues underlying the CRL, including that "one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that the equipment is unrelated to the manufacturer of DEFENCATH" and that the additional requested manual extraction study and airflow visualization study would be "completed in the next several weeks." Based on these and other statements, industry analysts and investors believed that the "the manufacturing issues are straightforward and can be resolved within weeks."

25. That was not the case, however. As analysts and investors learned on April 14, 2021, CorMedix would not be able to resubmit an NDA until the third quarter of 2021 ("3Q21") because it had to take additional steps for DefenCath's manufacturing process to meet FDA standards, including "[a]ddressing FDA's concerns regarding the qualification of the filling operation [that] may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath." On this news, CorMedix's stock price fell over 18%.

26. While disclosing that the Company's original proposed resolutions to

the deficiencies underlying the CRL were insufficient, the CorMedix Defendants assured investors that the Company was finally aligned with the FDA after "[k]ey representatives from both CorMedix and its CMO participated in a meeting…to address the deficiencies noted in the CRL." As a result, industry analysts (and investors) were "confident that there is a clear resolution plan agreed upon with the FDA to address the manufacturing CRL" and "anticipate[d] NDA resubmission in the next few months by around 3Q21 followed by FDA decision on the need for a site visit sometime in late 3Q21 or 4Q21[.]"

27. But then, on May 13, 2021, CorMedix disclosed that it would not be able to resubmit its NDA until the fourth quarter of 2021 ("4Q21") because "additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA." On this news, CorMedix's stock price fell nearly 20%.

28. The CorMedix Defendants, however, continued to tout the Company and its CMO's ability to resolve the manufacturing deficiencies and resubmit its NDA by the end of the year:

- 5/13/21: "[W]e have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency."
- 8/12/21: "[W]e are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021. … [W]e have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified[.]"

29. Industry analysts, and investors, still believed the CorMedix Defendants, particularly because they appeared to be intimately involved in resolving the manufacturing deficiencies rather than just leaving it to the CMO:

- 5/14/21: "Most importantly, the company is making good progress toward resubmission of the Defencath NDA, including completion of the manual extraction study. The company is advancing process qualification and validation activities, based on which it now expects to resubmit the Defencath NDA in 4Q21." (JMP Securities)

- 8/12/21: "Company remains on track to submit NDA in 4Q21. …[T]he process qualification of vial filling process appears to be in progress by the CMO with inputs from CRMD and outside consultant." (Truist Securities)

- 8/13/21: "The remaining process qualification and validation work requested by FDA is being completed by the third-party facility, in close collaboration with the CMC and regulatory teams of CorMedix and CMC consultants. CorMedix management affirmed that it remains in agreement with the third-party manufacturer on the appropriate steps to resolve the FDA's concerns. CorMedix is also working with the manufacturing facility to prepare for a potential on-site or remote inspection by the FDA." (JMP Securities)

30. Investors finally learned the full truth on September 7, 2021 when CorMedix disclosed that it "has encountered delays at its third-party [CMO]" relating to "issues that are unrelated to DefenCath manufacturing activities" and that "the timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA is uncertain[.]" On this news, CorMedix's stock price fell over 27%.

31. Moreover, these delays in resolving the manufacturing deficiencies

underlying the CRL and resubmitting the DefenCath NDA indicated that CorMedix did not have the "right team" to resolve the deficiencies, as confirmed on October 4, 2021. That day, CorMedix announced that, effective immediately, Defendant Baluch was retiring from his role as CEO and resigning from the Company's Board of Directors ("Board") and Defendant Armstrong was retiring from CorMedix.

32. CorMedix again confirmed that it did not have the "right team" to resolve the manufacturing deficiencies identified by the FDA when on November 9, 2021, Defendant Mounts admitted that "we have engaged [a] team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection."

33. In sum, throughout the Class Period, the CorMedix Defendants made materially false and misleading statements regarding the Company's business and operations. Specifically, they made false and/or misleading statements and/or failed to disclose that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath's NDA reflected those deficiencies; (iii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA; (iv) the foregoing deficiencies were far more likely to delay approval of the DefenCath NDA than the FDA's postponement of foreign

facility inspections due to COVID-19 restrictions; (v) despite the CRL, the CorMedix Defendants downplayed the true scope of the deficiencies with DefenCath's manufacturing process and at the facility responsible for manufacturing DefenCath; (vi) upon learning of new equipment at the facility manufacturing DefenCath, the CorMedix Defendants should have ensured that the CMO's protocols relating to changeover of manufacturing lines and visual inspections of drug products met current Good Manufacturing Practice ("cGMP") standards; (vii) deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and did cause contaminated vials in July 2021, which would delay the CMO's ability to obtain the data requested by the FDA demonstrating that the labeled volume could be consistently withdrawn from the vials; and (viii) as a result, the Company's public statements were materially false and misleading at all relevant times.

34. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

35. The claims asserted herein arise under and pursuant to §§ 11 and 15 of the 1933 Act (15 U.S.C. §§ 77k and 77o), and §§ 10(b) and 20(a) of the 1934 Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC

(17 C.F.R. § 240.10b-5).

36. This Court has jurisdiction over the subject matter of this action pursuant to § 22 of the 1933 Act, § 27 of the 1934 Act, and 28 U.S.C. § 1331.

37. Venue is proper in this Judicial District pursuant to § 22 of the 1933 Act, § 27 of the 1934 Act, and 28 U.S.C. § 1391(b). CorMedix is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant part of the acts and conduct complained of herein took place in this Judicial District.

38. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Plaintiff

39. Plaintiff purchased CorMedix securities at artificially inflated prices during the Class Period and traceable to the Offering Documents, as set forth in his certifications previously filed with the Court and incorporated herein by reference, and was damaged thereby, upon the revelation of the alleged corrective disclosures.

B. The CorMedix Defendants

40. Defendant CorMedix is a biopharmaceutical company that focuses on

developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company is a Delaware corporation with principal executive offices located at 300 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922. The Company has two wholly owned subsidiaries: CorMedix Europe GmbH (formed in 2013) and CorMedix Spain, S.L.U. (formed in May 2020). The Company's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "CRMD." Prior to February 2, 2021, the Company's common stock traded on the NYSE American ("NYSE") under the same ticker symbol.

41. Defendant Khoso Baluch ("Baluch") served as CorMedix's Chief Executive Officer ("CEO") and on its Board from October 2016 until he retired, effective October 4, 2021. Baluch and signed the Registration Statement for the Offering. Prior to joining CorMedix, Baluch served as Senior Vice President ("SVP") and President Europe, Middle East & Africa, and Chief Marketing Officer of UCB, SA. Baluch also worked for Eli Lilly and Company for 24 years, holding international positions spanning Europe, the Middle East and the U.S. in general management, business development, market access and product leadership.

42. Defendant Robert Cook ("Cook") served as CorMedix's Chief Financial Officer ("CFO") from February 1, 2017, until his employment agreement expired on January 31, 2020. Prior to joining CorMedix, Cook served as CFO of

Bioblast Pharma Ltd.; CFO and EVP at Strata Skin Sciences, Inc.; SVP and CFO at Immune Pharmaceuticals, Inc.

43. Defendant Matthew David ("David") has served as CorMedix's CFO and EVP since May 2020, and signed public filings incorporated into the Offering Documents. David joined CorMedix after serving as Head of Strategy at Ovid Therapeutics Inc, a late-stage clinical biopharmaceutical company, where he was responsible for financing strategy and investor relations.

44. Defendant Phoebe Mounts ("Mounts") was, at all relevant times, serving as EVP, General Counsel, and Secretary of CorMedix as well as its Head of Regulatory, Compliance & Legal. Prior to CorMedix, Mounts was a partner at Morgan, Lewis & Bockius LLP, where she had been providing legal services to the Company as outside counsel since 2013, with responsibility for developing its FDA regulatory strategies for Neutrolin.

45. Defendant John L. Armstrong (also referred to as "Jack") ("Armstrong") served as EVP for Technical Operations of CorMedix from March 2017 until his premature retirement, effective October 4, 2021. Prior to that, he was employed by the Company as a consultant beginning in November 2014, performing the same services that he performed as CorMedix's EVP for Technical Operations. The Company touted Armstrong's more than 45 years of experience in the pharmaceutical industry with broad senior level cross functional experience, as well

as his having held a number of general management positions. Prior to joining the Company, he was President of Correvio, a private pharmaceutical company supplying product to over 50 countries; President/CEO of Genaera Corporation; SVP of Urocor Corporation; CEO of Mills Biopharma; President of Oread CMO; President of Endo Laboratories (subsidiary of DuPont Merck); President of World-wide Manufacturing for DuPont Merck Pharmaceuticals; and Vice President Operations for Marion/ Marion Merrill Dow. Armstrong also held various roles in manufacturing, quality assurance, led integrated business systems development for three companies as well as having expertise in business development. Armstrong He is also a CPIM (Certified in Production and Inventory Management).

46. Pursuant to his Employment Agreement with the Company, executed on April 23, 2020, Armstrong was to serve as its EVP for 3 years, until April 2023. In announcing the agreement, CorMedix stated, in relevant part, that his "experience will be critical as we continue our preparations to commercialize Neutrolin, whether on our own or with a strategic or commercial partner."[12]

47. Defendants Baluch, Cook, David, Mounts, and Armstrong are referred

[12] *CorMedix Inc. Announces Contract Extension of Jack Armstrong as Executive Vice President and Head of Technical Operations*, GLOBENEWSWIRE (Apr. 23, 2020, 08:15 ET) ("4/23/20 Press Release"), https://www.globenewswire.com/news-release/2020/04/23/2020918/0/en/CorMedix-Inc-Announces-Contract-Extension-of-Jack-Armstrong-as-Executive-Vice-President-and-Head-of-Technical-Operations.html.

to herein as the "Officer Defendants;" CorMedix and the Officer Defendants are collectively referred to herein as the "CorMedix Defendants."

48. The adverse developments at issue here impacted the most central aspect, or the core, of CorMedix's business, operations, and revenue. Due to its prior financial struggles, the Company was particularly incentivized to take advantage of its U.S. prospects. During the Class Period, the CorMedix Defendants' communications to the public almost exclusively concerned the DefenCath NDA, and they repeatedly emphasized the Company's expertise and progress in developing and commercializing DefenCath for U.S. marketing.

49. As a result, the success of the DefenCath NDA was highly material to CorMedix's business during the Class Period, and indeed the Company represented to investors that all its products besides DefenCath had an "immaterial" impact on CorMedix's financial performance and business prospects. If CorMedix was not able to commercialize its main product in the U.S., it would have a material impact on the Company's profits and operations, for the simple reason that DefenCath was, at least during the relevant time period, the Company's sole focus. Indeed, during the Class Period, CorMedix focused nearly all of its manufacturing and product marketing to support the commercialization of DefenCath.

50. Analysts following the Company confirmed the paramount importance of achieving FDA approval of DefenCath and the sole focus of

CorMedix developing, marketing, and selling DefenCath in the U.S.

51. Given the substantial importance of FDA approval for DefenCath to the Company's financial performance, there is no doubt that the CorMedix Defendants would immediately have been aware of any concerns raised by the FDA regarding meeting CMC standards.

52. The Officer Defendants possessed the requisite scienter as they had the power and authority to control the contents of CorMedix's SEC filings, press releases, and other market communications. They were provided with copies of CorMedix's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with CorMedix, and their access to material information available to them but not to the public, the Officer Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Officer Defendants are liable for the false statements and omissions pleaded herein.

53. In addition, as alleged herein, the CorMedix Defendants acted with scienter in that they knew the public documents and statements disseminated or issued in the name of the Company were materially false and misleading; knew that such statements or documents would be disseminated or issued to the investing

public; and knowingly and substantially participated or acquiesced in disseminating or issuing of such statements or documents and in actions intended to manipulate the market price of CorMedix securities as primary violations of the securities laws.

54. The allegations herein also establish a strong inference that CorMedix as an entity acted with corporate scienter throughout the Class Period, as its officers, management, and agents, including, but not limited to, the Officer Defendants, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the concerns raised by the FDA from the investing public. Indeed, the FDA would have only communicated regarding these CMC issues with senior individuals at CorMedix who would have been in a position to establish its scienter. By concealing these material facts from investors, CorMedix maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

55. Moreover, given the extensive communications that the Officer Defendants had with analysts and investors, including Plaintiff, and the detail of their representations regarding their attention to detail and review of CMC standards, they

each made themselves aware of the Company's and FDA's actual (but undisclosed) findings with respect to the CMC data presented or had no factual basis to make such specific quantitative statements. In either event, the Officer Defendants were at least reckless with respect to the truth, and their scienter is imputable to the Company.

C. The Director Defendants

56. Defendant Janet Dillione ("Dillione") served as a director of CorMedix at all relevant times, and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

57. Defendant Myron Kaplan, M.D. ("Kaplan") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

58. Defendant Alan W. Dunton, M.D. ("Dunton") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

59. Defendant Steven Lefkowitz ("Lefkowitz") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

60. Defendant Paulo F. Costa ("Costa") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

61. Defendant Greg Duncan ("Duncan") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

62. Defendants Dillione, Kaplan, Dunton, Lefkowitz, Costa, and Duncan are referred to herein as the "Director Defendants."

63. The Director Defendants each participated in the preparation of, and signed and/or authorized the signing of, the Company's Offering Documents. By virtue of their positions as directors and/or senior officers of the Company, the Director Defendants were control persons of CorMedix. They each had direct and/or indirect business and/or personal relationships with other directors, officers and/or major shareholders of CorMedix. Because of their positions with CorMedix, and their access to material information available to them but not to the public, the Director Defendants knew of, or in the exercise of reasonable care should have known of, the existing yet undisclosed conditions and material risks detailed herein, which were either misrepresented in or omitted from the Offering Documents. As such, the Director Defendants are liable to Plaintiff and those similarly situated under the 1933 Act.

D. The Underwriter Defendants

64. Defendant B. Riley Securities, Inc. ("B. Riley") is a diversified financial services firm that, among other things, offers investment banking services

to public issuer of securities. Its headquarters are located at 299 Park Avenue, 21st Floor, New York, New York 10171.

65. Defendant Needham & Company, LLC ("Needham") is a diversified financial services firm that, among other things, offers investment banking services to public issuer of securities. Its headquarters are located at 250 Park Avenue, New York, New York 10177.

66. Defendants B. Riley and Needham are referred to herein as the "Underwriter Defendants."

67. On November 27, 2020, the Company issued a press release, later filed as a Current Report on Form 8-K with the SEC, signed by Defendant Baluch, announcing its Amended and Restated At Market Issuance Sales Agreement with B. Riley and Needham ("November Sales Agreement").

68. Defendants B. Riley and Needham acted as sale agents for CorMedix in connection with the Offering, and were, therefore, deemed to be an "underwriter" within the meaning of the 1933 Act and the compensation of Defendants B. Riley and Needham was deemed to be underwriting commissions or discounts.

69. Defendants B. Riley and Needham were not required to sell any specific amount, but were to act as sales agents of CorMedix, using commercially reasonable efforts consistent with their normal trading and sales practices. In connection with the sale of the common stock on the Company's behalf, they were

each entitled to compensation at a commission rate equal to 3% of the gross sales price per share sold.

70. Defendants B. Riley and Needham also demanded and obtained an agreement from the CorMedix Defendants to indemnify and hold them harmless from any liability under the federal securities laws.

71. Representatives of the Underwriter Defendants assisted CorMedix in planning the Offering, and therefore, had access to confidential corporate information concerning CorMedix's operations and financial prospects. In addition to availing themselves of virtually unlimited access to internal corporate documents, on information and belief, agents of the Underwriter Defendants met with CorMedix's lawyers, management, and top executives leading up to the Offering.

72. During these meetings, agreements were reached as to: (i) the strategy to best accomplish the Offering; (ii) the terms of the Offering, including the price at which CorMedix common stock would be sold; (iii) the language to be used in the Offering Documents; (iv) what disclosures would be made in the Offering Documents; and (v) what responses would be made to the SEC in connection with its review of the Offering Documents.

73. As a result of those frequent contacts and communications between the Underwriter Defendants and the CorMedix Defendants (as well as the Underwriter Defendants' direct involvement in material issues requiring disclosure,

including CorMedix's business performance and reported financial information), the Underwriter Defendants knew of, or in the exercise of reasonable care should have known of, the existing yet undisclosed conditions and material risks detailed herein, which were either misrepresented in or omitted from the Offering Documents.

74. Further, in connection with the Offering, the Underwriter Defendants marketed CorMedix stock to potential investors using materially false or misleading information about the Company, and/or omitted material information required to be disclosed in the Offering Documents. Moreover, the Underwriter Defendants' names were prominently displayed on the first page of the Prospectus Supplements filed in connection with the Offering.

75. Indeed, Defendants B. Riley and Needham also caused the Offering Documents to be filed with the SEC and to be declared effective in connection with the Offering. As such, the Underwriter Defendants are liable to Plaintiff and those similarly situated under the 1933 Act.

IV. THE 1933 ACT CLAIMS

A. Substantive Allegations Under the 1933 Act

76. This part of the Complaint only asserts strict liability and negligence claims based on the 1933 Act and neither alleges, nor sounds in, fraud.

77. As detailed below, the Offering Documents were negligently prepared and as a result contained untrue statements of material fact, omitted to state other

facts necessary to make statements not misleading, and were not prepared according to the rules and regulations governing the Offering Documents preparation.

78. For example, the Offering Documents failed to disclose that CorMedix knew or should have known before the effective date of the Offering Documents that its DefenCath NDA did provide sufficient CMC data necessary to achieve regulatory approval as the Company had represented, and that CorMedix was at risk of receiving a CRL from the FDA, delaying the approval process. In fact, as explained herein, the Offering Documents falsely and misleadingly represented contrary facts.

79. Any information concerning FDA approval of the Company's NDA for DefenCath, particularly information indicating that the NDA was incomplete and provided insufficient information and/or data as required by the FDA as represented to the market, was highly material to investors, because CorMedix's business model was primarily focused on achieving FDA approval and the entire thrust of its business was motivated by the development and commercialization of DefenCath in the U.S. Thus, any risk that the Company would be unable to market DefenCath domestically could be devastating to its business and future prospects.

1. CorMedix's pursuit of FDA approval of DefenCath

80. The Company has been developing its primary candidate, Neutrolin (later known as DefenCath) for the last decade, if not longer, claiming it will address a large unmet medical need and market opportunity. CorMedix's pursuit of U.S.

marketing approval for its lead product candidate began in late 2013, when the Company met with the FDA to determine the pathway forward for Neutrolin.

81. As part of the NDA process, a drug sponsor must provide the FDA with sufficient information to reach a decision as to "[w]hether the methods used in ***manufacturing*** the drug and the controls used to maintain the drug's quality are adequate to ***preserve the drug's identity, strength, quality, and purity***." 505(b)(1)(D), 21 C.F.R. § 314.50(d)(1)(i).

82. The FDA is a Founding Regulatory Member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH"), which has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective and high-quality medicines are developed, and registered and maintained in the most resource-efficient manner.[13] As such, the FDA plays a major role in developing each of the ICH guidelines, which the FDA then adopts and issues as industry guidance. *Id.*

83. Originally published in April 2009, ICH industry guidance titled "Q10 Pharmaceutical Quality System" describes a model for an effective quality

[13] U.S. FOOD & DRUG ADMIN., *Q13 Continuous Manufacturing Of Drug Substances And Drug Products* (October 2021), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q13-continuous-manufacturing-drug-substances-and-drug-products.

management system for the pharmaceutical industry.[14] This guidance states that as part of such a model pharmaceutical quality system, the **drug sponsor** "is ultimately responsible to ensure processes are in place to assure the control of outsourced activities and quality of purchased materials."[15] It further indicates that "[t]hese processes should incorporate quality risk management[,]" and with regard to manufacturing, should include the following critical activities:

- Assess "the suitability and competence" of potential CMOs to carry out the manufacturing audits, material evaluations, or other qualification criteria;
- Define "the responsibilities and communication processes for quality-related activities…in a written agreement" between the drug sponsor and the CMO; and
- Monitor and review "the performance" of the CMO, identifying and implementing any essential improvements. *Id.*

84. A drug sponsor's "*[s]enior management* has the ultimate responsibility to ensure an effective pharmaceutical quality system is in place to achieve the *quality objectives*, and that roles, responsibilities, and authorities are defined, communicated, and implemented throughout the company." *Id*. As such, senior management should:

- Participate in the design, implementation, ***monitoring, and maintenance***

[14] U.S. FOOD & DRUG ADMIN., *Q10 Pharmaceutical Quality System* (Apr. 2009), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q10-pharmaceutical-quality-system.

[15] U.S. FOOD & DRUG ADMIN., *Guidance for Industry - Q10 Pharmaceutical Quality System* (April 2009), https://www.fda.gov/media/71553/download.

of an effective pharmaceutical quality system;

- Demonstrate strong and visible support for the pharmaceutical quality system and ensure its implementation throughout their organization;
- Ensure a ***timely and effective communication and escalation process*** exists to raise quality issues to the appropriate levels of management;
- Define individual and collective roles, responsibilities, authorities, and inter-relationships of all organizational units related to the pharmaceutical quality system and ensure these interactions are communicated and understood at all levels of the organization;
- Conduct management reviews of process performance and product quality and of the pharmaceutical quality system;
- Advocate for continual improvement; and
- Commit appropriate resources. *Id*.

85. With regard to quality policy and planning, a drug sponsor's senior management should:

- Establish a quality policy that describes the overall intentions and direction of the company related to quality, including an expectation to comply with applicable regulatory requirements and facilitate continual improvement of the pharmaceutical quality system;
- Ensure the quality policy is communicated and understood by personnel at all levels of the company;
- Review the quality policy periodically for continuing effectiveness;
- Ensure the quality objectives to implement the quality policy are defined, communicated, supported by all relevant levels of the company, and aligned with the company's strategies and consistent with the quality policy;
- Provide appropriate resources and training to achieve the quality objectives; and

- Establish, monitor, regularly communicate, and act as appropriate upon performance indicators that measure progress against quality objectives. *Id.*

86. With regard to internal communications and management review, a drug sponsor's senior management should:

- Ensure appropriate communication processes are established and implemented within the organization which ensure the flow of appropriate information between all levels of the company and the appropriate and timely escalation of certain product quality and pharmaceutical quality system issues;

- Be responsible for pharmaceutical quality system governance through management review to ensure its continuing suitability and effectiveness; and

- Assess the conclusions of periodic reviews of process performance and product quality and of the pharmaceutical quality system. *Id.*

87. Since a drug sponsor has ultimate responsibility for product compliance, product, quality, safety, and efficacy, the drug sponsor should structure its organization to exercise proper oversight over manufacturing, quality control labs, quality assurance, regulatory affairs, and project management by:

- Ensuring that the personnel in the organization who are involved in the key areas have relevant knowledge and experience including technical expertise and authoring capabilities;

- Defining key oversight roles and including specific sponsor-CMO responsibilities in the quality agreement; and

- Documenting appropriate oversight details through Standard Operating Procedures ("SOPs"). [16]

[16] *5 Steps to Quality Oversight of Pharmaceutical Contract Manufacturing*

88. As part of its evaluation of a CMO, a drug sponsor should learn general prerequisites about the CMO, including: (i) the CMO's experience and regulatory history; (ii) the level of the CMO's adherence to cGMPs and SOPs; (iii) the quality of content in the required CMO documents; (iv) the level of hand-holding required; (v) the depth and breadth of the CMO's practical experience; (vi) the CMO's availability to formulate and fill when needed; (vii) the sufficiency of the CMO's staffing to allow for late-stage changes in the production plan; (viii) the experience and competency of the CMO's management team; (ix) the CMO's best practices; (x) the CMO's budget; (xi) the CMO's culture and possible language barriers and/or time zone differences; (xii) the availability of on-site audits; and (xiii) the CMO's system, process and/or procedures for maintaining privacy and confidentiality. *Id*.

89. With regard to manufacturing, a drug sponsor should learn about: (i) the CMO's expertise in manufacturing type/equipment; (ii) the CMO's process for authoring and/or transferring documents and/or batch records; and (iii) the CMO's ability to effectively correct manufacturing issues. *Id*.

90. With regard to quality control, a drug sponsor should learn about: (i) the CMO's expertise in analytical methodology/equipment; (ii) the CMO's ability to author analytical methods/validation protocols; (iii) the CMO's processes to

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Organizations (CMOs), COMPLIANCEONLINE https://www.complianceonline.com/resources/quality-oversight-of-pharmaceutical-contract-manufacturing-organizations.html.

address laboratory issues; and (iv) the level of involvement of the CMO's quality department and the CMO's ability to accommodate the product's specific needs. *Id*.

91. With regard to quality assurance, a drug sponsor should learn about: (i) the CMO's competencies with respect to quality assurance; (ii) the CMO's ability to author deviations, corrective and preventative actions ("CAPAs"), out-of-specification ("OOS") test result, and change controls; and (iii) the CMO's processes to address quality issues. *Id*.

92. With regard to regulatory affairs, a drug sponsor should learn about: (i) the CMO's understanding of the regulatory environment in which a product will be evaluated; (ii) the CMO's capabilities, experience and production environment to meet the product's specific requirements; and (iii) any and all audits of the CMO by several companies and regulatory agencies. *Id*.

93. With regard to product management, a drug sponsor should learn about: (i) the CMO's understanding of all sponsor requirements; (ii) the CMO's capability to maintain and adhere to a project plan; (iii) the CMO's level of commitment to and sense of the partnership; and (iv) the process for keeping the lines of communication open. *Id*.

94. A sponsor or manufacturer may make changes to the manufacturing of a drug during the drug development process, such as a new manufacturing site, formulation, purification column, equipment, or components. However, when

changes are made, the sponsor and/or manufacturer must demonstrate that the changes will not have an adverse impact on the drug's quality, safety, and efficacy.

95. To examine a drug manufacturer's compliance with cGMP regulations and determine if it has the necessary facilities, equipment, and ability to manufacture the drug, the FDA may perform a pre-approval inspection ("PAI").[17] The FDA conducts domestic and international PAIs for generic and innovator drug applications, and may inspect all facilities associated with an NDA, including drug component manufacturing (such as APIs, also known as drug substances), finished drug product manufacturing, and control testing laboratories.[18]

96. The PAI process begins with the manufacturer obtaining approval for its written procedures related to production, quality control, and quality assurance, and formulating supporting documentation therefrom.[19] Such written and approved procedures, and data therefrom, are necessary to identify quality problems which may link to other major systems for inspectional coverage. The manufacturers' adherence to written procedures must be verified through a site inspection whenever

[17] Denise DiGiulio, *What To Expect When Being Inspected*, U.S. FOOD & DRUG ADMIN., (July 15-16, 2015), https://www.fda.gov/media/92857/download.

[18] U.S. FOOD & DRUG ADMIN., *Compliance Program Guidance Manual – Chapter 46- New Drug Evaluation* (Apr. 12, 2010), https://www.fda.gov/media/71498/download.

[19] U.S. FOOD & DRUG ADMIN., *Compliance Program – Chapter 56 – Drug Quality Assurance, Drug Manufacturing Inspections* (Oct. 31, 2017), https://www.fda.gov/media/75167/download

possible. In advance of a site inspection, the FDA may request and inspect additional records or information within a reasonable timeframe, within reasonable limits, and in a reasonable manner under § 704(a)(4) of the FDCA.[20]

97. As a result of the COVID-19 pandemic, the FDA made changes to the PAI process and issued multiple temporary guidances related to manufacturing, supply chain and drug inspections during the Class Period.[21] One change was the implementation of "an interim process to communicate issues identified following a review of records or other information requested" under § 704(a)(4) of the FDCA. *Id*. As part of that process, the "FDA intend[ed] to communicate issues to facility representatives following the completion of its review of records or other information requested" under § 704(a)(4) and "plan[ned] to consider any formal responses regarding these issues, including documentation of corrective action, prior to taking an action on a pending application impacted by these issues, as feasible given user fee agreement and internal review program milestones." *Id*.

98. In addition, in September 2020, the FDA issued guidance related to "Resuming Normal Drug and Biologics Manufacturing Operations During the

[20] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Guidance for Industry – Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection* (Oct. 2014) https://www.fda.gov/media/86328/download.

[21] U.S. FOOD & DRUG ADMIN., *Manufacturing, Supply Chain, and Drug Inspections | COVID-19* (July 14, 2021) https://www.fda.gov/drugs/coronavirus-covid-19-drugs/manufacturing-supply-chain-and-drug-inspections-covid-19.

COVID-19 Public Health Emergency" ("September 2020 Guidance") which, *inter alia*, recommended manufacturers identify any deviations from established cGMP activities due to COVID-19 as well as any remediation and referred manufacturers to guidance the FDA had previously issued in March 2011 related to "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products[.]"[22] While this guidance gave "examples of delayed, reduced, or otherwise modified CGMP activities[,]" it confirmed that "CGMP requirements remain[ed] in effect during the COVID-19 public health emergency and this guidance [wa]s not intended to describe FDA's enforcement priorities." *Id.*

99. Based on the totality of the information available to the FDA, including the product information provided in the application and the available information about the facility or site, the FDA will take one of the following actions:

[22] U.S. FOOD & DRUG ADMIN., *Guidance for Industry - Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency* (September 2020) https://www.fda.gov/media/142051/download.

Planned Action	Facilities and Sites	Other FDA Drug Assessment Deficiencies
Approve the NDA	Available information supports the adequacy of the facilities and sites named in a pending application.	No deficiencies have been identified and the NDA otherwise satisfies the requirements for approval.
Issue a CRL with facility or site deficiencies	Available information from a prior inspection or other source identifies deficiencies about the facility or site, but the required inspection cannot be completed due to factors including travel restrictions.	If any other deficiencies, are identified by the assessment team, the CRL will include those deficiencies.
Issue a CRL without facility or site deficiencies	An inspection is necessary because there is a lack of information about the facility or site but cannot be completed due to factors including travel restrictions (a facility or site deficiency will NOT be issued; the facility or site issue will be a comment in the CRL).	Other deficiencies are identified by the assessment team. The CRL will contain those deficiencies.
Defer action (i.e., miss the PDUFA date)	An inspection is necessary because there is a lack of information about a facility or site and cannot be completed due to factors including travel restrictions (a facility or site deficiency will NOT be issued).	No deficiencies have been identified, and the application otherwise satisfies the requirements for approval.

100. If the FDA sends the sponsor a CRL, the letter will describe all the specific deficiencies that the FDA identified in the NDA and when possible, recommends actions for the sponsor to take to place its NDA in condition for approval.[23] A sponsor may resubmit its NDA, responding to the deficiencies detailed

[23] Applications for FDA Approval to Market a New Drug, Complete Response Letter to Applicant, 21 C.F.R. § 314.110 (2020), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.1

in the CRL that needed to be addressed prior to the NDA's approval.[24] Upon receipt of a resubmission, the FDA will determine whether the response is a complete response and if it is, the FDA will issue an acknowledgement letter classifying the resubmission as Class 1 or Class 2, and providing the performance goal date.[25]

101. Pursuant to PDUFA, the FDA is committed to reviewing and acting on a resubmission within six months. Any resubmission starts a new review cycle – two months for a Class 1 and six months for a Class 2 resubmission – which begins when the FDA receives the resubmission. This classification is based on the information submitted in response to the CRL. A Class 1 resubmission may relate to the drug's labeling, safety, stability, validation, post-marketing requirements or commitments, and/or final release testing. A Class 2 resubmission includes any item not specified as a Class 1 item, including items that warrant presentation to an advisory committee or a re-inspection.

102. At all relevant times, all of CorMedix's manufacturing processes were outsourced to third parties.[26] As such, the Company relied on third-party

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[24] CENTER FOR DRUG EVALUATION AND RESEARCH, *Manual of Policy and Procedures - Classifying Resubmissions of Original NDAs, BLAs, and Efficacy Supplements in Response to Complete Response Letters* (effective date Feb. 26, 2015), https://www.fda.gov/media/72727/download.

[25] The Class 1 or Class 2 distinction does not pertain to resubmissions of non-efficacy supplements (*i.e.* labeling and manufacturing supplements). *See* n.15.

[26] CorMedix, Inc., Quarterly Report (Form 10-Q) (Nov. 9, 2021).

manufacturers to produce sufficient quantities of drug product for clinical trials and commercial use. By the time of the Offering, the Company had been successfully managing and overseeing the commercial manufacturing of Neutrolin, for international sales, by third parties for several years.

103. To select the CMO for its U.S. drug product, CorMedix began the evaluation and selection process in late 2016.[27] After contacting and having initial discussions with 13 potential CMOs in the U.S. and internationally, and then conducting site visits, doing initial quality system reviews and reviewing proposals from several of those 13, the Company ultimately selected its CMO in 2017. *Id.*

104. On October 16, 2019, the Company announced a "Successful CMC Interaction with the FDA[.]"[28] CorMedix stated that "[t]he FDA was supportive of Neutrolin's proposed manufacturing program, including … the container closure and testing, and indicated that it will conduct a thorough review of all the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of NDA filing" and that "[n]o further CMC meetings with FDA

[27] *See Cormedix, Inc. – Special Call*, REFINITIV STREETEVENTS (Mar. 9, 2021, 01:30PM).

[28] *CorMedix Completes Successful CMC Interaction with the FDA*, GLOBENEWSWIRE. (Oct. 16, 2019), ("10/16/19 Press Release"), https://www.globenewswire.com/en/news-release/2019/10/16/1930488/0/en/CorMedix-Completes-Successful-CMC-Interaction-with-the- FDA.html.

[we]re planned prior to NDA submission."

105. Then, on November 14, 2019, during an investor call, Defendant Armstrong stated, in relevant part, that during the CMC interaction, the "FDA did request some additional data which [the Company was] working to complete" and noted that, in addition to conducting a thorough review of all CMC information, the FDA planned to "assess the commercial readiness of the various manufacturing facilities at the time of the NDA review."[29]

106. By July 8, 2020, CorMedix had completed its rolling submission for the DefenCath NDA, "despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission."[30] The Company assured investors that it "has not been informed of any delays by the FDA in the review of the NDA"[31] and that in order to complete the NDA, the Company "had to work through the [CMC] information[.]"[32]

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[29] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q3 2019 Results - Earnings Call Transcript*, SEEKING ALPHA (Nov. 14, 2019, 08:45 PM ET) ("3Q19 Call"), https://seekingalpha.com/article/4306874-cormedix-inc-crmd-ceo-khoso-baluch-on-q3-2019-results-earnings-call-transcript.

[30] *CorMedix Inc. Reports Submission of Defencath™ New Drug Application*, GLOBENEWSWIRE (July 8, 2020, 08:30 ET) ("7/8/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/07/08/2059263/0/en/CorMedix-Inc-Reports-Submission-of-Defencath-New-Drug-Application.html.

[31] CorMedix, Inc. Quarterly Report (Form 10-Q) (Aug. 10, 2020) ("2Q20 10-Q").

[32] *CorMedix Transcript CEO Khoso Baluch on Q2 2020 Results – Earnings Call*,

107. However, instead of ensuring that the DefenCath NDA contained all necessary information and/or data, based on well-established regulatory standards and the Company's ongoing dialogue with the FDA, and thus, preventing unnecessary risk of receiving a CRL and delaying the approval process, CorMedix submitted the DefenCath NDA without first competently verifying its completeness. At the time of the Offering, the Company's CMC program had been considered deficient by the FDA, the FDA notified CorMedix of these concerns, and CorMedix had already submitted additional data to the FDA in an effort to resolve these deficiencies, but such efforts were insufficient. Before the FDA had the time to fully assess the DefenCath NDA, CorMedix benefited from a highly inflated share price.

2. The Offering Documents Failed to Disclose That Risks Warned Of—That the NDA Approval Process Could Be Delayed as a Result of Insufficient Information and/or Data to Meet FDA Standards—Had Already Come to Pass.

108. On November 11, 2020, CorMedix filed Registration Statement No. 333-249901 with the SEC. The Registration Statement allowed the Company to offer and sell, from time to time, up to $100 million in the aggregate of any combination of the securities described therein, either individually or in units, in one or more offerings in amounts, at prices and on the terms that CorMedix would determine at the time of the offering (Offering). It also allowed the Company to

SEEKING ALPHA (Aug. 20, 2020) ("2Q20 Call"), https://seekingalpha.com/article/4367341-cormedixs-crmd-ceo-khoso-baluch-on-q2-2020-results-earnings-call-transcript.

offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

109. Registration Statement No. 333-249901 became effective on November 23, 2020, and on November 27, 2020, the Company filed as Exhibit 1.1 to Current Report Form 8-K, signed by Defendant Baluch, the November Sales Agreement with Defendants B. Riley and Needham. The November Sales Agreement permitted Defendants B. Riley and Needham to act as the Company's agents for the sale of shares of up to $25 million of the Offering. That same day, the Prospectus Supplement for the Offering, which forms part of the Offering Documents, was filed with the SEC.

110. During the year ended December 31, 2020, the Company sold 832,676 shares of common stock under the November Sales Agreement at the weighted average price of $8.69 per share and realized net proceeds of approximately $7.0 million. On February 5, 2021, CorMedix allocated an additional $25 million of the remaining $75 million available under the Offering. Giving effect to the additional $25 million, plus the $17.8 million available as of December 31, 2020, the Company had a total of $42.8 million available under the Offering. During January and February 2021, the Company sold an aggregate of 3,737,862 shares of common stock at an average price of $11.10 per share and

realized net proceeds of approximately $41.5 million.

111. The Prospectus Supplement for the Offering incorporated by reference, forming part of the Offering Documents, the following documents: (1) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020[33] ("2019 10-K"); (2) the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 11, 2020; (3) the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020; and (4) CorMedix's Current Reports on Form 8-K, filed with the SEC on: (i) February 3, 2020; (ii) February 4, 2020; (iii) February 6, 2020; (iv) April 8, 2020; (v) April 22, 2020; (vi) April 23, 2020; (vii) May 11, 2020; (viii) July 8, 2020; (ix) July 29, 2020; (x) August 31, 2020; (xi) September 17, 2020; (xii) October 14, 2020; and (xiii) November 2, 2020.

112. On February 3, 2020, pre-market, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Inc. Announces FDA Grant of Rolling Review of Neutrolin New Drug Application[.]"[34] That press release stated, in relevant part, that "***CorMedix remains***

[33] CorMedix, Inc., Annual Report (Form 10-K) (Mar. 16, 2020).

[34] *CorMedix Inc. Announces FDA Grant of Rolling Review of Neutrolin® New Drug Application*, GLOBENEWSWIRE (February 3, 2020, 08:15 ET) ("2/3/20 Press

on schedule for a potential NDA approval during the second half of 2020."

113. The statement referenced in ¶112 was materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

114. On March 16, 2020, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Inc. Reports Fourth Quarter and Full Year 2019 ["4Q19"] Financial Results and Provides Business Update" (the "3/16/20 Press Release").[35] That press release

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Release"), https://www.globenewswire.com/news-release/2020/02/03/1978704/0/en/CorMedix-Inc-Announces-FDA-Grant-of-Rolling-Review-of-Neutrolin-New-Drug-Application.html.

[35] *CorMedix Inc. Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update*, GLOBENEWSWIRE (March 16, 2020, 16:05 ET) ("3/16/20 Press Release"), https://www.globenewswire.com/news-release/2020/03/16/2001418/0/en/CORMEDIX-INC-REPORTS-FOURTH-QUARTER-AND-FULL-YEAR-2019-FINANCIAL-RESULTS-AND-PROVIDES-BUSINESS-UPDATE.html.

announced, in relevant part:

> ***[B]ecause the FDA has announced that it is postponing most foreign inspections through April and inspections outside of the US deemed mission-critical will still be considered on a case-by-case basis, we cannot predict if this will delay approval of the NDA***. Preapproval inspections of the manufacturing facilities relied upon for manufacturing of Neutrolin are required.

115. Defendant Baluch was further quoted in the 3/16/20 Press Release as stating that "[w]e plan to continue our filing schedule and to be on track for a decision in the second half of 2020, although we cannot at this time anticipate the impact on our timetable of the FDA's postponement of most foreign inspections."

116. That same day, CorMedix filed its 2019 10-K with the SEC, signed by Defendants Baluch, Kaplan, Dillione, Dunton, Khan, and Lekfowitz. The 2019 10-K included certain "Risks Related to Dependence on Third Parties" which had already materialized.

117. First, the 2019 10-K warned that the "[d]ata provided by collaborators and others upon which we rely that has not been independently verified ***could*** turn out to be false, misleading, or ***incomplete***." Specifically, the 2019 10-K stated that "[w]e rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. ***If such third parties provide*** inaccurate, misleading, or ***incomplete data***, our business, prospects, and results of operations could be materially adversely affected."

118. Second, the 2019 10-K warned that:

> Our contract manufacturers ***may not be able to comply with the applicable FDA regulatory requirements***, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval. They also generally must pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our product candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. ***If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP***, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in a product recall or prevent commercialization of our product candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

119. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendant Baluch certified that "[t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "***[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company***."

120. The statements referenced in ¶¶114-19 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; (iii) the foregoing deficiencies were far more likely to delay approval of the DefenCath NDA than the FDA's postponement of foreign facility inspections; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

121. On April 22, 2020, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing it had completed the sale of $5.5 million of NOL tax benefits through the New Jersey Technology Business Tax Certificate Transfer Program.[36] In that press release, Defendant Baluch was quoted as stating, in relevant part "***[w]e have remained on***

[36] *CorMedix Completes Sale of $5.5 Million of NOL Tax Benefits through New Jersey Technology Business Tax Certificate Transfer Program*, GLOBENEWSWIRE (April 22, 2020, 8:00 ET) ("4/22/20 Press Release"), https://www.globenewswire.com/news-release/2020/04/22/2019921/0/en/CorMedix-Completes-Sale-of-5-5-Million-of-NOL-Tax-Benefits-through-New-Jersey-Technology-Business-Tax-Certificate-Transfer-Program.html.

schedule towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic."

122. The statements referenced in ¶121 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; (iii) the foregoing deficiencies were far more likely to delay approval of the DefenCath NDA than delays at the FDA due to the coronavirus pandemic; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

123. On May 11, 2020, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Inc. Reports First Quarter 2020 ["1Q20"] Financial Results and Provides Business Update[.]"[37] That press release quoted Defendant Baluch as stating, in relevant part,

[37] *CorMedix Inc. Reports First Quarter 2020 Financial Results and Provides Business Update*, GLOBENEWSWIRE (May 11, 2020, 1610 ET) ("5/11/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/05/11/2031451/0/en/CorMedix-Inc-Reports-First-Quarter-2020-Financial-Results-and-Provides-Business-Update.html.

that "[w]e have been working remotely since mid-March, a transition we have made with little disruption and as a result ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***."

124. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2020 ("1Q20 10-Q") signed by Defendant Baluch. The 1Q20 10-Q stated that "***[a]s a result of the COVID-19 outbreak, or similar pandemics, and related 'shelter in place' orders and other public health guidance measures, we have and may in the future experience disruptions*** that could materially and adversely impact our clinical trials, business, financial condition and results of operations." Such "[p]otential disruptions" included "***interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems[.]***"

125. The 1Q20 10-Q further stated that:

> ***The extent to which the [COVID-19] outbreak impacts our business***, preclinical studies and clinical trials ***will depend on future developments***, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. ***If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the***

manner and on the timelines presently planned could be materially and negatively impacted.

126. Appended as exhibits to the 1Q20 10-Q were substantively the same SOX certifications referenced in ¶119, *supra*, signed by Defendant Baluch.

127. The statements referenced in ¶¶123-26 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; (iii) the foregoing deficiencies were far more likely to delay approval of the DefenCath NDA than any delays at the CMO due to the COVID-19 outbreak; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

128. On July 8, 2020, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, during pre-market hours, announcing that it had completed submitting the DefenCath NDA with the FDA for CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter (the "7/8/20 Press Release"). That press release stated, in relevant part, that "***all of the modules for the Defencath™ [NDA] have been***

submitted to the [FDA]" and that "***there has been ongoing dialogue with FDA as it reviews the submitted modules***."

129. The 7/8/20 Press Release also quoted Defendant Baluch, who represented, in relevant part, that CorMedix was "very pleased to have ***completed the submission of the NDA***, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission."

130. The statements referenced in ¶¶128-29 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the ongoing dialogue with the FDA was reflecting the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

131. On August 10, 2020, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting the Company's results for the second quarter of 2020 ("2Q20") and providing a business update (the "8/10/20 Press Release"). That press release represented, *inter alia*, that

CorMedix had "***[c]ompleted the rolling submission and review of the [NDA] for Defencath to the FDA*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via catheter."

132. Additionally, the 8/10/20 Press Release quoted Defendant Baluch, who stated, in relevant part, that "[w]e were pleased to announce ***the completion of our rolling submission for Defencath last month*** and look forward to providing updates on the acceptance for filing from FDA" and "[w]e believe ***we have the team***, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

133. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2020, signed by Defendant Baluch (the "2Q20 10-Q"). The 2Q20 10-Q discussed the Company's DefenCath NDA submission with the FDA, stating, *inter alia*, that "***[i]n March 2020, the Company began the modular submission process for the NDA for Defencath*** for the prevention of CRBSI in hemodialysis patients, and recently announced ***on July 8, 2020, that submission of all modules for the NDA was completed***" and that "[t]he Company has not been informed of any delays by the FDA in the review of the NDA[.]"

134. The 2Q20 10-Q also stated that "[a]s a result of the COVID-19 outbreak, or similar pandemics, and related 'shelter in place' orders and other public

health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations." Such "[p]otential disruptions" included "interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems[.]"

135. The 2Q20 10-Q further stated that:

> ***The extent to which the [COVID-19] outbreak impacts our business***, preclinical studies and clinical trials ***will depend on future developments***, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. ***If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.***

136. Appended as exhibits to the 2Q20 10-Q were substantively the same SOX certifications referenced in ¶119, *supra*, signed by Defendants Baluch and David.

137. The statements referenced in ¶¶131-36 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the ongoing dialogue with the FDA was reflecting the existence

of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) the facility manufacturing DefenCath would be installing new equipment about which the CMO and/or CorMedix was failing to provide sufficient information; (iv) in light of the foregoing deficiencies and omissions, the FDA was unlikely to approve the DefenCath NDA; (v) the foregoing deficiencies and omissions were far more likely to delay approval of the DefenCath NDA than any delays at the CMO due to the COVID-19 outbreak; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

138. On August 31, 2020, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing the FDA's acceptance for filing and priority review of the DefenCath NDA, setting a PDUFA date of February 28, 2021, for the completion of its review (the "8/31/20 Press Release"). That press release stated that the FDA "noted that ***it is planning to hold an advisory committee meeting to discuss the [NDA] application*** and that ***it had not identified any potential review issues*** at this time."

139. The 8/31/20 Press Release also quoted Defendant Mounts, who asserted, in relevant part, that "we look forward to ***continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA*** to address

an unmet medical need."

140. The statements referenced in ¶¶138-39 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA's plan to hold an advisory committee meeting reflected the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) the facility manufacturing DefenCath would be installing new equipment about which the CMO and/or CorMedix was failing to provide sufficient information; (iv) in light of the foregoing deficiencies and omissions, the FDA was unlikely to approve the DefenCath NDA; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

141. On November 5, 2020, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting the Company's results for the third quarter of 2020 ("3Q20"), and providing a business update (the "11/5/20 Press Release"). That press release represented, in relevant part, that "***CorMedix continues its interactions with the FDA regarding the ... NDA[] for Defencath™*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via central venous catheter. The FDA has tentatively scheduled the

previously announced meeting of the Antimicrobial Drugs Advisory Committee for January 14, 2021 to discuss the Defencath NDA."

142. The 11/5/20 Press Release also quoted Defendant Baluch, who stated, in relevant part, that "[w]e look forward to discussing Defencath with the Antimicrobial Drugs Advisory Committee in January, ahead of the February 28, 2021 PDUFA date for the product" and that "[w]e believe ***we have the team***, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

143. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2020 (the "3Q20 10-Q"). The 3Q20 10-Q contained substantively the same statements as referenced in ¶133, *supra*, discussing the submission process for the DefenCath NDA while also advising, *inter alia*, that "[t]he FDA noted that it is planning to hold an advisory committee meeting to discuss the application and that ***it had not identified any potential review issues*** at this time[,]" and that "[t]he Company has not been informed of any delays by the FDA in the review of the NDA, but ... ***pre-approval inspections are required for manufacturing sites***."

144. The 3Q20 10-Q also stated that "[a]s a result of the COVID-19 outbreak, or similar pandemics, and related 'shelter in place' orders and other public

health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations." Such "[p]otential disruptions" included "interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems[.]"

145. The 3Q20 10-Q further stated that:

> ***The extent to which the [COVID-19] outbreak impacts our business***, preclinical studies and clinical trials ***will depend on future developments***, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. ***If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.***

146. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications referenced in ¶119, *supra*, signed by Defendants Baluch and David.

147. The statements referenced in ¶¶141-46 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the continued FDA interactions and the FDA's plan to hold an

advisory committee meeting reflected the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) the facility manufacturing DefenCath would be installing new equipment about which the CMO and/or CorMedix was failing to provide sufficient information; (iv) in light of the foregoing deficiencies and omissions, the FDA was unlikely to approve the DefenCath NDA; (v) the foregoing deficiencies and omissions were far more likely to delay approval of the DefenCath NDA than any delays at the CMO due to the COVID-19 outbreak; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

148. By the commencement of this action, CorMedix's stock price closed at $6.42 per share on July 22, 2021, representing a 26% decline from the average $8.69 per share sold by the end of 2020 and a 42% decline from the average $11.10 per share sold in January and February 2021. On December 15, 2021, CorMedix securities closed at $4.84 per share.

B. Failure to Disclose Information Required by Items 303 and 105 of Regulation S-K

149. In addition to the materially false and misleading statements in the Offering Documents identified above, Defendants also violated their affirmative

obligations to provide certain material information in the Offering Documents as required by applicable SEC rules and regulations.

150. Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303 ("Item 303"), requires the Offering Documents to "[d]escribe any known trends or uncertainties that have had or that the registrant reasonable expects will have a materially favorable and unfavorable impact on the sales or revenues or income from continuing operations."

151. In May 1989, the SEC issued an interpretive release on Item 303 ("1989 Interpretive Release"), stating, in pertinent part, as follows:

> Required disclosure is based on currently known trends, events, and uncertainties that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.
>
> * * *
>
> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

152. Further, the 1989 Interpretive Release sets forth the following test to determine if disclosure under Item 303(a) is required:

> Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:
>
> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.

> (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

153. By the Offering, the FDA had already communicated insufficiency in the CMC program presented by CorMedix for the DefenCath NDA. Thus, whether the FDA would approve the NDA based on the data and application submitted was a known uncertainty that was then having, and would continue to have, an unfavorable impact on the Company's revenues and income from continuing operations, and was therefore required to be disclosed in the Offering Documents but was not.

154. In addition, Item 505 of SEC Regulation S-K, 17 C.F.R. § 229.105 ("Item 105"), required, in the "Risk Factors" section of the Offering Documents, a discussion of the most significant factors that made the offering risky or speculative, and that each risk factor adequately describe the risk.

155. The Offering Documents failed to disclose that there was an increased risk that CorMedix's NDA would be denied based on deficient information because the FDA had expressed concern regarding the data supporting the CMC program. Because this risk was not disclosed, Defendants (other than Cook, Mounts and Armstrong) violated Item 105.

C. Class Action Allegations by the 1933 Act Class

156. Plaintiff brings this action as a class action pursuant to the Federal Rules of Civil Procedure ("Rules") 23(a) and 23(b)(3) on behalf of all persons who purchased CorMedix securities pursuant or traceable to the Offering pursuant to the Offering Documents. This class asserts claims only for violations of §§ 11 and 15 of the 1933 Act, 15 U.S.C. §§ 77k and 77o. This class does not assert any claims sounding in fraud. Any person who did not purchase or acquire their CorMedix shares directly in or traceable to the Offering and pursuant to the corresponding Offering Documents is not included in the 1933 Act Class. Also excluded from the 1933 Act Class are Defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

157. The members of the 1933 Act Class are so numerous that joinder is impracticable. The Offering involved the issuance and sale of at least 4.57 million shares of CorMedix securities, which were publicly traded on the NYSE and the NASDAQ following the sale of common stock pursuant to the Offering. While the exact number of 1933 Act Class members is unknown to Plaintiff at this time, he believes that there are at least thousands of members in the proposed 1933 Act Class. Record owners and other members of the 1933 Act Class may be identified from records maintained by CorMedix or its transfer agents and may be notified of the

pendency of this action by mail, using the form notice similar to that customarily used in securities class actions.

158. Plaintiff's claims are typical of the claims of the 1933 Act Class, as all 1933 Act Class members were and are similarly affected by Defendants' conduct.

159. Plaintiff will fairly and adequately protect the interests of the 1933 Act Class members and has retained counsel competent and experienced in securities class action litigation.

160. Common questions of law and fact exist as to all 1933 Act Class members and predominate over any questions solely affecting individual 1933 Act Class members. Among the common questions of law and fact are:

(a) whether Defendants violated the 1933 Act;

(b) whether the Offering Documents misrepresented and/or omitted material facts in violation of the 1933 Act; and

(c) whether and to what extent 1933 Act Class members have sustained damages and the proper measure of damages.

161. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual 1933 Act Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible and impracticable, for them to individually redress the alleged wrongs done to them. There will be no difficulty in managing this action as a class action.

COUNT I
Violations of § 11 of the 1933 Act
(Against All Defendants Other than Cook, Mounts and Armstrong)

162. Plaintiff repeats and re-alleges the above allegations in ¶¶1-20, 34-41, 43, 56-161 as if fully set forth herein.

163. This Cause of Action is brought pursuant to § 11 of the 1933 Act, 15 U.S.C. § 77k, on behalf of the 1933 Act Class, against all Defendants other than Defendants Cook, Mounts and Armstrong. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of § 11, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

164. Section 11 gives rise to liability to certain defendants enumerated therein if "any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading. . . ." 15 U.S.C. § 77k(a).

165. Among others, § 11 identifies the following categories of defendants as those who may be liable thereunder: (a) "every person who signed the registration statement"; (b) "every person who was a director of (or person performing similar functions) . . . the issuer at the time of the filing of the part of the registration statement with respect to which his liability is asserted"; (c) "every person who, with

his consent, is named in the registration statement as being or about to become a director, person performing similar functions, or partner"; and (d) "every underwriter with respect to such security." 15 U.S.C. § 77k(a)(1)-(3), (5).

166. The Registration Statement, Prospectus Supplement, and the Company's other public filings incorporated by reference, which formed the Offering Documents for the Offering, contained inaccurate and misleading statements of material fact, omitted facts necessary to render statements therein non-misleading, and omitted to state material facts required to be stated therein.

167. CorMedix is the registrant for the Offering. Defendants named herein were responsible for the contents and disseminating the Offering Documents, and the Director Defendants, Baluch and David each signed and/or authorized the signing of the Registration Statement or were designated therein, or in the incorporated documents, as director-nominees. The Underwriter Defendants marketed and underwrote the Offering and sold CorMedix common stock to investors.

168. As the issuer of the shares, CorMedix is strictly liable to Plaintiff and the 1933 Act Class for the Offering Documents' material misstatements and omissions. Signatories of the Offering Documents and the other defendants named herein are also strictly liable to Plaintiff and the 1933 Act Class for such material misstatements and omissions.

169. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds to believe that the statements in the Offering Documents were complete, accurate or non-misleading.

170. By reason of the conduct alleged herein, each Defendant named herein violated, and/or controlled a person who violated, § 11 of the 1933 Act.

171. Plaintiff purchased CorMedix securities pursuant to the Offering Documents.

172. Plaintiff and the 1933 Act Class have sustained damages. The value of CorMedix securities has declined substantially subsequent and due to Defendants' violations.

173. At the time of their purchases of CorMedix securities, Plaintiff and other members of the 1933 Act Class were without knowledge of the facts concerning the wrongful conduct alleged herein.

174. Less than one year elapsed from the time Plaintiff discovered, or reasonably could have discovered, the facts upon which this complaint is based to the time that Plaintiff filed this action. Less than three years have elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time this action was filed.

COUNT II
Violations of § 15 of the 1933 Act
(Against the Director Defendants, Baluch and David)

175. Plaintiff repeats and re-alleges the above allegations in ¶¶1-20, 56-161 as if fully set forth herein.

176. This Cause of Action is brought pursuant to § 15 of the 1933 Act against the Director Defendants, Baluch and David. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of § 15, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

177. Where a violation of § 11 occurs, § 15 gives rise to liability as to "[e]very person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under section 77k [§11. . ." 15 U.S.C. § 77o(a). Control persons under § 15 are "liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable[.]" *Id.*

178. As detailed herein, each of the Director Defendants, Baluch and David, committed primary violations of the 1933 Act, or are directly responsible and primarily liable for any such violations, by committing conduct in contravention of § 11.

179. The Company controlled the Director Defendants, Baluch and David, each of whom signed or authorized the signing and/or filing of the Offering Documents.

180. The Director Defendants, Baluch and David, each were control persons of CorMedix by virtue of their positions as directors and/or senior officers of the Company. They each had direct and/or indirect business and/or personal relationships with other directors, officers and/or major shareholders of CorMedix. Alternatively, the Company controlled the Director Defendants, Baluch and David, given the influence and control the Company possessed and exerted over them.

181. By reason of the conduct alleged herein, these Defendants violated § 15 of the 1933 Act, and Plaintiff and the 1933 Act Class have suffered harm as a result.

V. THE 1934 ACT CLAIMS

Defendants' Fraudulent Scheme to Hide Manufacturing Deficiencies

1. Defendants misleadingly portrayed FDA approval of CorMedix's proposed manufacturing program for DefenCath as a given.

182. In the months leading up to the Class Period, CorMedix had begun to focus on ensuring its commercial manufacturing met FDA standards – and had made it clear to investors that the Company knew what it was doing in that regard. In August 2019, Defendant Armstrong specifically assured investors that:

> CorMedix has been manufacturing and selling Neutrolin outside the U.S. for the last five years. We have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at three different manufacturing sites. ***This should give you comfort that we understand Neutrolin's manufacturing, technical, analytical processes as well as the quality controls and the systems that go with it.*** … ***And importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved***.
>
> … Many companies, particularly small, inexperienced companies, overlook the importance of the CMC section that is required for the NDA. At CorMedix, we have not done that. ***We have been diligently working and interacting with the FDA on this topic continually during the product development in the U.S.***
>
> Our press release of July 9 was an update on our ongoing discussions with FDA to ensure that all the CMC information required for the NDA will be in place. It was intended to be ***a clear signal from CorMedix to life science investors that we understand the importance of manufacturing data and that we are on top of it.***
>
> In addition, we are now in the process of finalizing the supply chain and distribution network for the initial product that will be used for launch in the U.S. The initial finished product will be manufactured in Europe.[38]

183. Accordingly, from the start of the Class Period, Defendants gave investors the misleading impression that the FDA was fully on-board with CorMedix's proposed manufacturing program for DefenCath, and thus would approve it no later than the second half of 2020. Defendants' statements also led

[38] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q2 2019 Results - Earnings Call Transcript*, SEEKING ALPHA (Aug. 13, 2019, 04:30 PM ET), https://seekingalpha.com/article/4285328-cormedix-inc-crmd-ceo-khoso-baluch-on-q2-2019-results-earnings-call-transcript.

investors to believe that the Company has already conducted due diligence and quality control on its CMO's manufacturing facilities to ensure that they would pass any and all FDA inspections.

184. For example, on October 16, 2019 and then again on November 14, 2019, the Company declared that "[t]he FDA was supportive of Neutrolin's proposed manufacturing program…. No further CMC meetings with FDA are planned prior to NDA submission."[39] Defendant Armstrong reiterated those same sentiments during the Company's 3Q19 Call.

185. Defendant Baluch also stated in the 10/16/19 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Cook, that "Neutrolin can be approved in the second half of 2020" (*id.*), which the Company confirmed

[39] *CorMedix Completes Successful CMC Interaction with the FDA*, GLOBENEWSWIRE (Oct. 16, 2019, 2019, 08:15 ET) ("10/16/19 Press Release"), https://www.globenewswire.com/news-release/2019/10/16/1930488/0/en/CorMedix-Completes-Successful-CMC-Interaction-with-the-FDA.html; *CorMedix Inc. Reports Third Quarter 2019 Financial Results and Provides Business Update*, GLOBENEWSWIRE (Nov. 14, 2019, 16:05 ET) ("11/14/19 Press Release"), https://www.globenewswire.com/en/news-release/2019/11/14/1947574/0/en/CorMedix-Inc-Reports-Third-Quarter-2019-Financial-Results-and-Provides-Business-Update.html;,

was "on schedule" in February 2020[40] and "maintain[ed]" in May 2020.[41]

186. Moreover, because Defendants touted CorMedix's five-year track record of successfully manufacturing and selling Neutrolin and the Company's top-notch personnel, investors believed CorMedix knew what it was doing with regard to manufacturing. Specifically, during the 3Q19 Call, Defendant Armstrong touted that "CorMedix has been manufacturing and selling Neutrolin outside the US for the last five years. We've successfully carried out technical transfer and validation of the manufacturing process which is enable the successful production of product at three different manufacturing sites." In addition, Defendant Baluch boasted about:

> The significant experience Phoebe [Mounts] brings in regulatory, Jack [Armstrong] in manufacturing and supply chain, Paul in medical affairs and Liz in clinical operation, coupled with my Cialis and Byetta launch experience in the US just to name a few recent launches makes for a winning team. Together, we have a combined experience of over 170 years in the pharmaceutical business.

187. As the COVID-19 pandemic swept through the world in the spring of 2020, Defendants warned of possible delays on the side of the FDA relating to in-person inspections of foreign manufacturing facilities potentially being postponed, but declared that CorMedix and its personnel were "on track" with ensuring the FDA

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[40] *CorMedix Inc. Announces FDA Grant of Rolling Review of Neutrolin® New Drug Application*, GLOBENEWSWIRE (Feb. 3, 2020, 08:15 ET) ("2/3/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/02/03/1978704/0/en/CorMedix-Inc-Announces-FDA-Grant-of-Rolling-Review-of-Neutrolin-New-Drug-Application.html.

[41] 5/11/20 Press Release.

had what it needed to approve the Company's manufacturing by the end of 2020:

- Baluch: "We plan to continue our filing schedule and to be on track for a decision in the second half of 2020, although we cannot at this time anticipate the impact on our timetable of the FDA's postponement of most foreign inspections." (3/16/20 Press Release)

- Mounts: "We cannot predict if this will delay approval of the NDA because pre-approval inspections of the manufacturing facilities relied upon for manufacturing of Neutrolin are required." (4Q19 Call)[42]

- Baluch: "We have remained on schedule towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic." (4/22/20 Press Release)

- Mounts: "[W]e are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020. We are all very cognizant of preparing an NDA that is complete and provides all of the information in the agency's required format to ensure an efficient review. We focused on discussions with FDA in 2019 to make sure that we understood the FDA's expectations to evaluate the manufacturing…" (1Q20 Call)

- Baluch: "[T]he effort to move the regulatory process forward with the FDA is on track. We are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020." (1Q20 Call)

188. By July 8, 2020, CorMedix had completed its rolling submission for the DefenCath NDA, "despite the limitations imposed by the COVID-19 pandemic,

[42] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q4 2019 Results - Earnings Call Transcript*, SEEKING ALPHA (Mar. 16, 2020, 04:30 PM ET) ("4Q19 Call"), https://seekingalpha.com/article/4332346-cormedix-inc-crmd-ceo-khoso-baluch-on-q4-2019-results-earnings-call-transcript.

which delayed some required laboratory testing and our submission."[43] The Company assured investors that it "has not been informed of any delays by the FDA in the review of the NDA"[44] and that in order to complete the NDA, the Company "had to work through the [CMC] information[.]"[45]

189. Capitalizing on the Company's positive public image following the completion of its NDA submission, on July 27, 2020, CorMedix announced its plans to offer shares of its common stock in an underwritten public offering.

190. On March 9, 2018, CorMedix filed Registration Statement No. 333-223562 with the SEC. The Registration Statement (using a "shelf" registration process) allowed the Company to offer, from time to time, up to $70,000,000, any combination of the securities described therein, either individually or in units, in one or more offerings in amounts, at prices and on the terms that the Company would determine at the time of the offering. On April 16, 2018, the Prospectus for the Registration Statement, became effective.

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[43] *CorMedix Inc. Reports Submission of Defencath™ New Drug Application*, GLOBENEWSWIRE (July 8, 2020, 08:30 ET) ("7/8/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/07/08/2059263/0/en/CorMedix-Inc-Reports-Submission-of-Defencath-New-Drug-Application.html.

[44] CorMedix, Inc. Quarterly Report (Aug. 10, 2020) ("2Q20 10-Q").

[45] *CorMedix Transcript CEO Khoso Baluch on Q2 2020 Results – Earnings Call*, (Aug. 20, 2020) ("2Q20 Call"), https://seekingalpha.com/article/4367341-cormedixs-crmd-ceo-khoso-baluch-on-q2-2020-results-earnings-call-transcript.

191. On July 28, 2020, the Company filed with the SEC, the Prospectus Supplement for the public offering announced on July 27, 2020. Thereafter, CorMedix offered and sold 5,111,110 shares of common stock, which included the exercise by the underwriters of their option to purchase additional shares, at a public offering price of $4.50 per share for gross proceeds of approximately $23.0 million.

192. As the FDA was reviewing the DefenCath NDA, CorMedix further informed investors that it was working closely with the FDA and was not being told of any issues in the NDA. For example, on August 31, 2020, when announcing the FDA's acceptance of the NDA for priority review and setting of a February 28, 2021 PDUFA date, CorMedix "noted that [the FDA] is planning to hold an advisory committee meeting to discuss the [NDA] application and that it had not identified any potential review issues at this time."[46] The Company maintained the same messaging on November 5, 2020 when it reported its 3Q20 financial results, simply warning that it "has not been informed of any delays by the FDA in the review of the NDA, but … pre-approval inspections are required for manufacturing sites."[47]

193. To investors then, the FDA review of the DefenCath NDA (including

[46] *CorMedix Inc. Announces FDA Acceptance for Filing and Priority Review of New Drug Application for Defencath*, GLOBENEWSWIRE (Aug. 31, 2020, 07:47 ET) ("8/31/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/08/31/2086071/0/en/CorMedix-Inc-Announces-FDA-Acceptance-for-Filing-and-Priority-Review-of-New-Drug-Application-for-Defencath.html.

[47] CorMedix, Inc., Quarterly Report (Form 10-Q) (Nov. 5, 2020) ("3Q20 10-Q").

the manufacturing information) appeared to be going well. Particularly when, on November 18, 2020, CorMedix announced it "has been notified that based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle."[48] At the same time, Defendant Baluch assured investors of the high "level of engagement between FDA and the CorMedix team during the NDA review process" and Defendant Mounts confirmed the team's "continu[ed] effort and dialogue with the [FDA] to ensure that the priority review process can be completed expeditiously." *Id*. On these statements, CorMedix's share price rose over 11%.

194. Capitalizing on the continued artificial price of its securities, on November 27, 2020, CorMedix announced the completion of its November Sales Agreement with the Underwriter Defendants, and the Company filed its Prospectus Supplement for the Offering. During the year ended December 31, 2020, the Company sold 832,676 shares of common stock under the Offering at a weighted average price of $8.69 per share and realized net proceeds of approximately $7.0

[48] *CorMedix Inc. Announces FDA Decision That Advisory Committee Meeting for New Drug Application for Defencath is Not Needed*, GLOBENEWSWIRE (Nov. 18, 2020, 08:30 ET), ("11/18/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/11/18/2129199/0/en/CorMedix-Inc-Announces-FDA-Decision-That-Advisory-Committee-Meeting-for-New-Drug-Application-for-Defencath-is-Not-Needed.html.

million, and during January and February 2021, the Company sold an aggregate of 3,737,862 shares of common stock at an average price of $11.10 per share and realized net proceeds of approximately $41.5 million.

195. Since Defendants did not ensure that CorMedix's CMO met cGMP standards prior to the FDA's requests for information from the CMO, the FDA observed numerous deficiencies during its review of the CMO's facilities. At no point, however, did Defendants inform investors that the FDA's requests for additional information from CorMedix's CMO based in Western Europe reflected the FDA's ongoing concern about potential deficiencies in DefenCath's manufacturing process and at the CMO's manufacturing facility.

196. Investors were therefore shocked when, before markets opened on March 1, 2021, instead of announcing FDA approval, CorMedix disclosed receipt of a CRL denying approval.[49] The Company explained that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility" and "is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials." *Id*. On this news, CorMedix's stock price fell $8.16 per share, or 54.4%,

[49] *CorMedix Receives Complete Response Letter From FDA for DefenCath™ Catheter Lock Solution*, GLOBENEWSWIRE (Mar. 1, 2021, 08:30 ET) ("3/1/21 Press Release"), https://www.globenewswire.com/en/news-release/2021/03/01/2184292/0/en/CorMedix-Receives-Complete-Response-Letter-From-FDA-for-DefenCath-Catheter-Lock-Solution.html.

to close at $6.84 per share on March 3.

197. Unbeknownst to its investors, however, CorMedix had failed to give a complete picture of what was in the CRL. Unfortunately, this is a common practice for sponsors that receive CRLs. A cross-sectional study published in April 2015 comparing the content of CRLs and the sponsor's associated public announcements found that when press releases were issued, they omitted most of the statements in the CRLs.[50] In the press releases analyzed, only 14% of the deficiencies cited by the FDA were noted in the announcement. *Id*. The study concluded that "[p]ress releases are incomplete substitutes for the detailed information contained in [CRLs]." *Id*.

2. Despite the CRL, Defendants misleadingly maintained that CorMedix was on track to resolve manufacturing deficiencies and resubmit its NDA for FDA approval.

198. After disclosing the CRL, Defendants knew they had damage control to do. As analyst Joon Lee of Truist Securities ("*Truist*") noted on March 1, 2021, "CRMD disclosed this AM it has received CRL due to third party manufacturing issues without disclosing the nature of the issue. ***This comes as a surprise as the***

[50] Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study. *Compare* Asher Mullard, *Sponsors rarely disclose Refuse to File letters, finds study of regulatory transparency gap in* Nature Reviews – Drug Discovery (Vol. 20, Apr. 2021) and, Peter Lurie, Harinder S. Chahal, Daniel W. Sigelman, Sylvie Stacy, Joshua Sclar, Barbara Ddamulira, *Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study*, BMJ 2015;350:h2758 (Apr. 8, 2015).

product has already been in production and commercial in the EU, albeit at limited capacity." (Emphasis in original).[51]

199. Defendants immediately spoke with Mr. Lee, giving him enough assurances to issue another analyst report that day – one that emphasized that "today's 40% selloff appears overdone" ("March 1 Truist Report").[52] With regard to the "manual extraction study[,]" the report specifically explained that:

> [M]gmnt stated that the vials contain an 'overage' to ensure that labeled volume can be extracted…. It appears to be a routine process and believes a separate study is unlikely to be needed as long as company can convince that FDA that the 'overage' included is sufficient to enable extracting of labeled volume.

200. At the same time, the March 1 Truist Report confirmed that CorMedix's "Mgmnt was aware that the FDA has requested additional information from the EU based third party manufacturer." *Id.* But Defendants had chosen not to provide investors this material information earlier for them to be aware of it then.

201. Thus, despite being forced to disclose manufacturing deficiencies as a result of the CRL, Defendants continued to mislead investors. For example, based on his conversation with the Company's management, Mr. Lee issued yet another analyst report titled "Additional Color from Management on Contract Manufacturer

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[51] Joon Lee, M.D., Ph.D., Les Sulewski, *CRL Due To CMC Issues. No Deficiencies Related to Efficacy Or Safety of Defencath*, TRUIST SECURITIES (Mar. 1, 2021).

[52] Joon Lee, M.D., Ph.D., Les Sulewski, *Selloff On CMC Issues Overdone. REIT BUY But PT To $30 (-$5) On Launch Delays*, TRUIST SECURITIES (Mar. 1, 2021).

in Question" the next day.[53] That report confirmed that CorMedix "management reiterated that the CMO manufactures drugs sold in the U.S.[,] implying some level of FDA inspection in the past that passed FDA's standards" and "alluded that the CMO is experienced in handling drug/device combos similar in scope to Defencath." *Id.*

202. Then, during the conference call CorMedix hosted on March 9, 2021, pre-market, to provide additional color on the manufacturing deficiencies raised by the FDA in the CRL ("CRL Call"), Defendants made statements downplaying the issues underlying the CRL and confirming that the Company's personnel had the skills and experience to successfully resolve the issues, including, *inter alia*:

- Mounts: "Based on our discussions with the CMO, we believe these deficiencies can be resolved in the coming weeks."
- Mounts: "For example, one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that ***the equipment is unrelated to the manufacturer of DEFENCATH*** because FDA has requested details to assess the impact to production readiness for DEFENCATH."
- Mounts: "We have submitted data to FDA to demonstrate performance with the specifications but we intend to conduct the requested manual extraction study and expect it to be completed in the next several weeks."
- Mounts: "Another deficiency identifies concerns an ***airflow visualization study***, and will likely necessitate repeating the study

[53] Joon Lee, M.D., Ph.D., Les Sulewski, *Additional Color from Management on Contract Manufacturer in Question*, TRUIST SECURITIES (Mar. 2, 2021).

to demonstrate adequate dynamic conditions in the study, which we believe ***can be accomplished in the next several weeks***."

- Baluch: We believe we have within CorMedix and the CMO, the resources and capabilities to achieve successful resolution of the manufacturing deficiencies to the satisfaction of the FDA.[54]

203. In addition, Defendant Armstrong detailed:

> [T]he process CorMedix followed in selecting our drug product CMO. We began the evaluation and selection process in late 2016 because of the long lead time. We had several criteria in the selection process: quality system, capacity and cost. We contacted and had initial discussions with 13 potential CMOs in the U.S. and internationally. After the initial assessments, we narrowed the list of several, including U.S. and international sites for more detailed assessment. We then conducted site visits, did an initial quality system review, reviewed proposals and ultimately selected our CMO in 2017. **We followed the industry standard practice of executing a manufacturing agreement, quality agreement and development of a project plan for technical, analytical transfer and validation with the associated documentation**. Thereafter, we proceeded to execute on the project plan, which included an engineering batch and 3 commercial scale drug product validation batches.

Id.

204. Based on these and other statements during the CRL Call, industry analysts following CorMedix believed the manufacturing deficiencies underlying the CRL were manageable and would be resolved within weeks:

- "Based on the details provided on this morning's conference call, we believe the manufacturing issues are straightforward and can be

[54] *Cormedix, Inc. – Special Call*, REFINITIV STREETEVENTS (Mar. 9, 2021, 01:30PM).

resolved within weeks."[55] (JMP)

- "Update Suggest Fixes Are Manageable."[56] (Truist)
- "We did not hear anything on yesterday's call that in our view justifies heightened concern… ."[57] (Wainwright)

205. The Company maintained the same messaging on March 30, 2021, including during its fourth quarter and full year 2020 ("4Q20") earnings conference call with analysts and investors[58]:

- Baluch: "[W]e have ***the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified."
- Mounts: "The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains ***on track*** based on the progress we have made."
- Mounts: "We make sure that we -- where we could, ***we provided information that was responsive*** to the deficiency."
- Mounts: "[T]he issue was planned expansion at the manufacturing facility, which involved installation of new equipment. That is new equipment non-intended for manufacturer of DEFENCATH. So, ***the***

[55] Jason N. Butler, PhD, Roy Buchanan, PhD. *Details on Defencath Manufacturing CRL Issues Support Potential for Rapid Resolution*, JMP SECURITIES LLC ("JMP") (Mar. 9, 2021).

[56] Joon Lee, M.D., Ph.D., Les Sulewski, *Update Suggest Fixes Are Manageable. More To Follow*, TRUIST SECURITIES, INC. ("Truist") (Mar. 9, 2021).

[57] Raghuram Selvaraju, Ph.D., *Update Conference Call Clarifies Regulatory Situation; Reiterate Buy*, H.C. WAINWRIGHT & CO, LLC ("Wainwright & Co.") (Mar. 10, 2021).

[58] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q4 2020 Results – Earnings Call Transcript*, SEEKING ALPHA (Mar. 30, 2021, 06:10 PM ET) ("4Q20 Call"), https://seekingalpha.com/article/4416889-cormedix-inc-crmd-ceo-khoso-baluch-on-q4-2020-results-earnings-call-transcript.

> ***information that has been used and is in place is the appropriate equipment*** for DEFENCATH manufacture."

206. Based on these and other statements made by the Company on March 30, 2021, industry analysts continued to believe that CorMedix would resolve the manufacturing deficiencies and resubmit its NDA in May 2021:

- "[O]ur enthusiasm for Defencath remains unchanged, especially in light of no issues found with the drug during the FDA review."[59] (Truist)
- "[B]ased on mgmnt commentaries, our base case is that CMC issues can be resolved expeditiously without the need for an FDA site visit. We look forward to updates from the mid-April FDA meeting." (Truist)
- "The company remains on track to meet with the FDA regarding the manufacturing CRL for Defencath in mid-April. We remain of the view … that the deficiencies can be quickly resolved, supporting an NDA resubmission in May."[60] (JMP)
- "Management commented that it did include new information to address FDA's questions in the meeting request package, further reinforcing our view that the CRL can be quickly resolved and the NDA submitted in May." (JMP)

207. After its April meeting with the FDA, however, CorMedix was forced to disclose on April 14, 2021 in a press release that it would have to take more steps than previously disclosed to meet the FDA's requirements for DefenCath's

[59] Joon Lee, M.D., Ph.D., Les Sulewski, *Our Enthusiasm for Defencath Remains Unchanged Despite Cash Overhang And Regulatory Uncertainty*, TRUIST SECURITIES, INC. (Mar. 30, 2021).

[60] Jason N. Butler, PhD, Roy Buchanan, PhD, *4Q20: Update: On the Offensive for Defencath in 2021*, JMP SECURITIES LLC (Mar. 31, 2021).

manufacturing process.[61] As a result, the Company's NDA resubmission would not occur until 3Q21. On this news, the Company's stock price fell over 18%. As analysts following CorMedix noted, "[i]nvestors appear to be responding negatively to the [C]ompany announcing today that it has meet with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [CRL] to CorMedix and the Post-Application Action Letter received by the third-party manufacturer (CMO) from FDA for the [NDA] for DefenCath[.]"[62]

208. But also in the April 2021 Press Release, Defendants assured investors that the Company was finally aligned with the FDA after "[k]ey representatives from both CorMedix and its CMO participated in a meeting…to address the deficiencies noted in the CRL", and it would be meeting its manufacturing requirements shortly. Industry analysts were thus reassured of a 2021 NDA resubmission:

- "We are confident that there is a clear resolution plan agreed upon with the FDA to address the manufacturing CRL… The company and its CMO will complete all of the necessary items to resolve the CRL prior to the resubmission… We are maintaining our base-case

[61] *CorMedix Has Meeting With FDA on DefenCath Catheter Lock Solution NDA*, GLOBENEWSWIRE (Apr. 14, 2021, 09:00 ET) ("4/14/21 Press Release"), https://www.globenewswire.com/news-release/2021/04/14/2210054/0/en/CorMedix-Has-Meeting-With-FDA-on-DefenCath-Catheter-Lock-Solution-NDA.html.

[62] Amit Chowdhry, *CRMD Stock: Over 10% Decrease Intraday Explanation*, PULSE 2.0 (Apr. 14, 2021) https://pulse2.com/crmd-stock-nasdaq-cormedix-over-10-decrease-intraday-explanation/.

view for the launch of Defencath in 4Q21."[63] (JMP)

- "Based on today's update we anticipate NDA resubmission in the next few months by around 3Q21 followed by FDA decision on the need for a site visit sometime in late 3Q21 or 4Q21[.]"[64] (Truist)

209. On April 14, 2021, the FDA provided new guidance for remote evaluations of drug manufacturing site evaluations to accommodate the challenges of physical site visits during the ongoing pandemic.[65] After speaking to Defendants about this new guidance, *Truist* analyst Lee noted that "[w]e spoke to management this morning on this document. Management believes it certainly opens the door for a virtual visit as opposed to a physical on-site visit…We still believe resubmission is likely in 3Q21 with FDA update in 4Q21."[66]

210. But after markets closed on May 13, 2021, CorMedix disclosed that it would not be able to resubmit its NDA until 4Q21 because "additional process qualification will be needed with subsequent validation to address the deficiencies

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[63] Jason N. Butler, PhD, Roy Buchanan, PhD, *Post-FDA-Meeting Update for Defencath*, JMP SECURITIES LLC (Apr. 14, 2021).

[64] Joon Lee, M.D., Ph.D., Les Sulewski, *CRMD Met With The FDA. Need For Site Visit To Be Determined Post NDA Resubmission*, TRUIST SECURITIES, INC. (Apr. 14, 2021).

[65] U.S. FOOD & DRUG ADMIN., *FDA Provides Guidance on Remote Interactive Evaluations for Oversight of Drug Facilities During COVID-19* (Apr. 14, 2021), https://www.fda.gov/news-events/press-announcements/fda-provides-guidance-remote-interactive-evaluations-oversight-drug-facilities-during-covid-19.

[66] Joon Lee, M.D., Ph.D., Les Sulewski, *Path To Remote Virtual Inspection Appears Feasible Based on Recent FDA Guidance*, TRUIST SECURITIES, INC. (Apr. 15, 2021).

identified by FDA."[67] On this news, CorMedix's stock price fell nearly 20%.

211. Defendants still, however, touted the Company's ability to resolve the manufacturing deficiencies and resubmit its NDA by the end of the year:

- 5/13/21 Press Release: "[W]e have the right team and resources to accomplish this as we advance DefenCath through the regulatory approval process." (Baluch)
- 1Q21 10-Q: "The Company and the CMO continue to work closely to ensure that the identified deficiencies are resolved prior to resubmission of the DefenCath NDA."
- 1Q21 Call: "[W]e have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency."
- 8/12/21 Press Release: "CorMedix … remains on schedule to re-submit the DefenCath™ New Drug Application in the fourth quarter of 2021." (Baluch)[68]
- 2Q21 Call: "[W]e are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021. … We remain confident that we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified[.]" (Baluch)[69]

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[67] *CorMedix Inc. Reports First Quarter 2021 Financial Results and Provides Business Update*, GLOBENEWSWIRE (May 13, 2021 16:01 ET) ("5/13/21 Press Release"), https://www.globenewswire.com/news-release/2021/05/13/2229438/0/en/CorMedix-Inc-Reports-First-Quarter-2021-Financial-Results-and-Provides-Business-Update.html.

[68] *CorMedix Inc. Reports Second Quarter and Six Month 2021 Financial Results and Provides Business Update*, GLOBENEWSWIRE (August 12, 2021 16:01 ET) ("8/12/21 Press Release"), https://www.globenewswire.com/news-release/2021/08/12/2280058/0/en/CorMedix-Inc-Reports-Second-Quarter-and-Six-Month-2021-Financial-Results-and-Provides-Business-Update.html.

[69] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q2 2021 Results – Earnings Call Transcript*, *SEEKING ALPHA* (Aug. 12, 2021) ("2Q21 Call"),

- 2Q21 Call: "[W]e remain on schedule to resubmit the new drug application or NDA in the fourth quarter of 2021. … [W]e are working closely with the[manufacturing facility] and CMC consultants engaged by CorMedix to ensure that we are addressing FDA concerns appropriately." (Mounts)

212. Industry analysts, and investors, still believed Defendants, particularly because they gave the impression that they were intimately involved in resolving the manufacturing deficiencies rather than just leaving it to the CMO:

- 5/14/21: "Most importantly, the company is making good progress toward resubmission of the Defencath NDA, including completion of the manual extraction study. The company is advancing process qualification and validation activities, based on which it now expects to resubmit the Defencath NDA in 4Q21. … Additionally, this morning the company appointed a Chief Commercial Officer with deep experience and demonstrated success in the renal disease space." (JMP)[70]

- 8/12/21: "Company remains on track to submit NDA in 4Q21. …[T]he process qualification of vial filling process appears to be in progress by the CMO with inputs from CRMD and outside consultant. The new batches manufactured for these studies will need to undergo new stability tests but mgmnt state that it will not be a rate limiting step to ultimate approvability of DefenCath." (Truist)[71]

- 8/13/21: "The most important update from the quarter was that CorMedix affirmed it remains on track to resubmit in 4Q21 the Defencath NDA for the prevention of catheter-related bloodstream

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https://seekingalpha.com/article/4448910-cormedix-inc-crmd-ceo-khoso-baluch-on-q2-2021-results-earnings-call-transcript.

[70] Jason N. Butler, PhD, Roy Buchanan, PhD, *1Q21 Update: Diligently Advancing to the Defencath NDA Re-Submission*, JMP SECURITIES LLC (Apr. 14, 2021).

[71] Joon Lee, M.D., Ph.D., Les Sulewski, *DefenCath Remains On Track For NDA Resubmission 4Q21. Reit BUY*, TRUIST SECURITIES, INC. (Aug. 12, 2021).

infections." (JMP)[72]

- 8/13/21: "The remaining process qualification and validation work requested by FDA is being completed by the third-party facility, in close collaboration with the CMC and regulatory teams of CorMedix and CMC consultants. CorMedix management affirmed that it remains in agreement with the third-party manufacturer on the appropriate steps to resolve the FDA's concerns. CorMedix is also working with the manufacturing facility to prepare for a potential on-site or remote inspection by the FDA." (JMP)

213. Investors thus did not learn the full truth until pre-market, September 7, 2021, CorMedix disclosed that it "has encountered delays at its third-party [CMO]" and that "the timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA is uncertain[.]"[73] In other words, "CMO delay br[ought] uncertainty to Defencath NDA resubmission timelines[.]"[74] On this news, CorMedix's stock price fell over 27%.

214. Securities analysts recognized that investors had reacted negatively to the continued unresolved manufacturing deficiencies which were delaying the Company's NDA resubmission.

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[72] Jason N. Butler, PhD, Roy Buchanan, PhD, *2Q21 Update: On Track for Defencath NDA Resubmission in 4Q21*, JMP SECURITIES LLC (Aug. 13, 2021).

[73] *CorMedix Inc. Announces Regulatory Update*, GLOBENEWSWIRE (Sept. 7, 2021, 08:30 ET) ("9/7/21 Press Release"), https://www.globenewswire.com/news-release/2021/09/07/2292524/0/en/CorMedix-Inc-Announces-Regulatory-Update.html.

[74] Jason N. Butler, PhD, Roy Buchanan, PhD, *Defencath Announcement Increases Timing Uncertainty, but Fundamental Impact Unlikely*, JMP SECURITIES LLC (Sept. 7, 2021).

- CorMedix "slumps 20.6% premarket after the company provided an update with respect to its resubmission timeline for the DefenCath [NDA]." (Seeking Alpha)[75]

- CorMedix's "stock was getting crushed on Tuesday, with shares down 23.7% as of 11 a.m. EDT … after the company announced that it 'has encountered delays at its third-party contract manufacturer.' These delays will push back CorMedix's refiling for [FDA] approval of its DefenCath antibacterial and antifungal catheter lock solution by an undetermined amount of time." (Motley Fool)[76]

215. Moreover, these delays in resolving the manufacturing deficiencies underlying the CRL and resubmitting CorMedix's NDA indicated the Company did not have the "right team" to resolve the CMO's deficiencies, as confirmed on October 4, 2021.[77] That day, CorMedix announced that, effective immediately, Defendant Baluch was retiring from his role as CEO and resigning from the Company's Board and Defendant Armstrong was retiring from CorMedix.

216. As of the filing of this Complaint, the Company still does not know when it will be resubmitting the DefenCath NDA. In reporting its 3Q21 financial

[75] Mamta Mayani, *CorMedix plummets 21% after facing delays at contract manufacturer*, CORMEDIX INC. (Sept. 7, 2021, 09:15 AM ET), https://seekingalpha.com/news/3737518-cormedix-plummets-24-after-facing-delays-at-contract-manufacturer.

[76] Keith Speights, *Why CorMedix Stock Is Getting Crushed Today*, THE MOTLEY FOOL (Sept. 7, 2021, 11:20 AM), https://www.fool.com/investing/2021/09/07/why-cormedix-stock-is-getting-crushed-today/.

[77] *CorMedix Inc. Announces Executive Leadership Changes*, CORMEDIX, INC. (Oct. 4, 2021), https://www.cormedix.com/cormedix-inc-announces-executive-leadership-changes/.

results on November 9, 2021, CorMedix confirmed it was still working on "address[ing] the deficiencies identified at the manufacturing facility" and still did not "have clarity on the submission timeline."[78] Likewise, during the 3Q21 earnings conference call, Defendant Mounts specifically noted that:

> As noted by Matt [David], and as we disclosed in early September, there was a delay as a result of issues that the CMO that were **unrelated to the manufacture of DEFENCATH**. We have been able to resume manufacturing activities and are continuing to complete the work that is required to address the deficiencies identified by the FDA.
>
> Specifically, we have discussed previously that FDA had identified deficiencies involving activities associated with the vial filling line for DEFENCATH at the CMO, in particular, to target filling up volumes.
>
> After analyzing available data, parameters of the filling operation were adjusted, and we determined that qualification of the filling operation was required. It will require some time to complete testing and preparation of documentation to resubmit the manufacturing module of the new drug application or NDA for DEFENCATH.
>
> Until we have completed all of the testing, we will not be able to give specific guidance regarding the timing of resubmission.[79]

[78] *Cormedix Inc. Reports Third Quarter 2021 Financial Results And Provides Business Update*, CORMEDIX, INC. (Nov. 9, 2021), https://www.cormedix.com/cormedix-inc-reports-third-quarter-2021-financial-results-and-provides-business-update/.

[79] CorMedix Inc., *CEO Matt David on Q3 2021 Earnings Call Transcript* (Nov. 09, 2021, 07:58 PM ET) ("3Q21 Earnings Call"), https://seekingalpha.com/article/4467632-cormedix-inc-crmd-ceo-matt-david-on-q3-2021-earnings-call-transcript.

217. In addition, during the Question-and-Answer ("Q&A") portion of the 3Q21 Earnings Call, Defendant Phoebe explained that:

> The vial filling activities that we're currently undertaking involve manufacturing of DEFENCATH and it's during that process that we are doing the testing that FDA requires to demonstrate that the process is in fact qualified. So, it's a validation process that's ongoing that actually requires the manufacturing activities, which is why when there was a delay, we had a problem in doing the manufacturing.
>
> So, now that the manufacturing has resumed, we can continue generating the data and the documentation that we need to submit to FDA. And the new batches are part of that process. So, obviously, we're manufacturing batches as we go and analyzing those batches to collect the data and can generate documentation.

3. Defendants continue to conceal the identity of CorMedix's CMO for commercialization in the U.S., and thus, during the Class Period, investors were in the dark about potential impact of the CMO's lack of experience with FDA inspections and maintaining cGMP standards.

218. Defendants know, but still have not disclosed, the identity of CorMedix's CMO, thus leaving investors in the dark about risks related to the CMO's manufacturing of DefenCath until they materialized and were disclosed by Defendants.[80] Nonetheless, Plaintiff's investigation has uncovered which CMO CorMedix most likely contracted with to manufacture DefenCath. This Spanish manufacturer had little prior experience with FDA inspections and its manufacturing

[80] Plaintiff has filed a Freedom of Information Act (FOIA) request with the FDA seeking information related to CorMedix's manufacturing. In the event Plaintiff receives information from the FDA that is pertinent to this action, Plaintiff reserves the right to amend this complaint.

processes and protocols did not comply with certain cGMP standards.

219. In May 2020, CorMedix formed a wholly-owned subsidiary in Madrid, Spain while the country was beginning to ease its COVID-19 lockdown restrictions, but did not explain why to investors. The reason appears to be that the manufacturing facility of the Company's most likely CMO is in Madrid, Spain: ROVI Contract Manufacturing, S.L., owned by Laboratorios Farmacéuticos ROVI ("ROVI"). This facility specializes in aseptic filling small volume parenterals in pre-filled syringes and vials, with an annual capacity of 180 million syringes and 50 million vials.[81]

220. By July 9, 2020, Defendants knew or should have known that ROVI had agreed to do "large-scale, commercial fill-finish manufacturing of Moderna's" COVID-19 vaccine candidate at ROVI's Madrid facility.[82] As part of the deal, ROVI was to "provide vial filling and packaging capacity by procuring **a new production line and equipment for compounding, filling, automatic visual inspection and labeling** to support production of hundreds of millions of doses of the vaccine

[81] *ROVI Contract Manufacturing*, OUTSOURCING-PHARMA.COM (https://www.outsourcing-pharma.com/Suppliers/ROVI-Contract-Manufacturing (last visited Dec. 3, 2021).

[82] ROVI, *Moderna and ROVI Announce Collaboration for Outside the United States Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate* (July 9, 2020), https://roviservices.com/wp-content/uploads/2020/12/ROVI_Press-release_Moderna_1.pdf.

candidate … to supply markets outside of the U.S. starting in early 2021." *Id.* Based on guidelines by and/or communications with the FDA, CorMedix knew or should have known that it needed to provide the FDA information about any new production line and/or equipment at the facility manufacturing DefenCath – even if it was unrelated to the manufacturing of DefenCath.

221. By April 29, 2021, Defendants knew or should have known that ROVI would be investing in new production lines at its Madrid facility "where it bottles, or 'fills and finishes' Moderna vaccines for markets" other than the US in order to "double its capacity to bottle" the vaccine.[83] Again, based on FDA guidelines (*see supra* ¶94) and/or communications with the FDA, CorMedix knew or should have known that it needed to provide the FDA information about any new production lines at the facility manufacturing DefenCath – even if they were unrelated to the manufacturing of DefenCath.

222. By July 27, 2021, Defendants knew or should have known about contaminants in vials manufactured by ROVI which required ROVI to conduct testing, as Moderna had publicly warned customers outside the U.S. of temporary delays in its COVID-19 vaccine shipments resulting from a testing operation by

[83] Reuters, *Spain's Rovi Will Double Its Capacity to Bottle Moderna's COVID-19 Vaccines*, U.S. NEWS (Apr. 29, 2021, 02:52 AM), https://www.usnews.com/news/world/articles/2021-04-29/spains-rovi-will-double-its-capacity-to-bottle-modernas-covid-19-vaccines.

overseas manufacturing partners – one of whom was known to be ROVI.[84] Based on FDA guidelines (*see supra* ¶92) and/or communications with the FDA, CorMedix knew or should have known that it needed to provide the FDA with information about testing being done at the facility manufacturing DefenCath – even if it was unrelated to the manufacturing of DefenCath.

223. By August 26, 2021, Defendants knew or should have known that Japan temporarily halted the use of over 1.6 million doses of Moderna's COVID-19 vaccine after "[u]nspecified contaminants were discovered in nearly 40 doses of the vaccine at eight locations across Japan, prompting the decision to pull the lot that included them, as well as two other lots produced at the same location[.]"[85] Later that day, ROVI specifically stated that "the origin of this incident may be in one of its manufacturing lines and it was conducting an investigation following the standard procedure for such cases" as well as putting on hold "two adjacent lots … as a precaution."[86]

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[84] *Moderna warns of Covid-19 vaccine delivery delays for customers outside US*, RT.com (July 27, 2021, 18:43), https://www.rt.com/news/530406-moderna-covid-vaccine-delivery-disruption/.

[85] Ben Dooley and Hisako Ueno, *Japan halts 1.6 million doses of the Moderna vaccine over contamination worries*, THE NEW YORK TIMES (Oct. 28, 2021) (https://www.nytimes.com/2021/08/26/world/japan-moderna.html.

[86] Clara-Laeila Laudette, *Rovi investigating possible Moderna vaccine contamination, no safety issues so far*, REUTERS (Aug. 26, 2021, 12:27 PM EDT), https://www.reuters.com/world/europe/rovi-investigating-possible-moderna-vaccine-contamination-no-safety-issues-so-2021-08-26/.

224. By September 1, 2021, Defendants knew or should have known the results of ROVI's investigation as they were made public.[87] ROVI's root cause analysis report identified "the most probable cause of the particulates" as "related to friction between two pieces of metal installed in the stoppering module of the production line due to an incorrect set-up. The two pieces are the star-wheel and the stoppers feeding device piece which feeds stoppers into the star-wheel." ROVI believed "that this condition occurred during the assembling of the line prior to production of [the impacted batch] and was a result of improper alignment during a line changeover before starting this batch." *Id.* Moderna independently analyzed and confirmed that the particulate were grade 316 stainless steel, which was consistent with the root cause investigation. *Id*. ROVI took the following steps to correct and prevent future defects:

- Full inspection of the manufacturing line;
- Improving standard operating procedure for changeover of manufacturing line; and
- Setting alert inspection limits in the automatic visual inspection, as an internal process control.

Id.

[87] *Laboratorios Farmaceuticos Rovi S A : ROVI informs about the joint statement from Moderna and Takeda on the investigation of suspended lots of the vaccine*, MARKETSCREENER (Sept. 1, 2021, 03:52 PM EST), https://www.marketscreener.com/quote/stock/LABORATORIOS-FARMACEUTICO-388853/news/Laboratorios-Farmaceuticos-Rovi-S-A-ROVI-informs-about-the-joint-statement-from-Moderna-and-Takeda-36303039/.

225. By October 1, 2021, Defendants knew or should have known that ROVI had discovered contaminants in some vials in July 2021, but allowed supplies from that same production to pass inspection and ship to Japan.[88]

226. Because Defendants did not disclose the identity of CorMedix's CMO and/or other material facts about the CMO's lack of experience with FDA inspections and maintaining cGMP standards when adding new production lines and equipment or changing drug products in the manufacturing line, and instead touted the Company's successful interactions with the FDA and manufacturing of DefenCath, investors had no reason to expect a CRL and delays in the resubmission due to manufacturing deficiencies related to the CMO's process for manufacturing DefenCath and protocols relating to changeover of manufacturing lines and visual inspections of drug products.

B. Materially False and Misleading Statements and Omissions During the Class Period[89]

227. The Class Period begins on October 16, 2019, when pre-market, the Company issued a press release entitled "CorMedix Completes Successful CMC

[88] Rocky Swift, *Japan's Takeda says 'human error' caused contamination of Moderna vaccines*, REUTERS (Oct. 1, 2021, 01:17 AM EDT), https://www.reuters.com/world/asia-pacific/japans-takeda-says-human-error-caused-contamination-moderna-vaccines-2021-10-01/.

[89] The particular portions of the statements giving rise to an alleged duty to disclose material facts in order for the statements to not be misleading are bold and italicized in this Section.

Interaction with the FDA" ("10/16/19 Press Release"). That same day, the Company filed the 10/16/19 Press Release with the SEC as Exhibit 99.1 to the Current Report on Form 8-K, signed by Defendant Cook pursuant to the requirements of the Exchange Act. The 10/16/19 Press Release stated, in relevant part, that:

> ***The FDA was supportive of Neutrolin's proposed manufacturing program***, including the active pharmaceutical ingredients (API), the container closure and testing, and indicated that ***it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of NDA filing. No further CMC meetings with FDA are planned prior to NDA submission.***

228. Defendant Baluch was further quoted in the 10/16/19 Press Release as stating that "[w]e anticipate that ***Neutrolin can be approved in the second half of 2020*** and we intend to launch Neutrolin commercially in the US promptly after its approval either by ourselves or with a partner."

229. The statements referenced in ¶¶227-28 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; and (iii) as a result, the Company's public statements were materially false and

misleading at all relevant times.

230. On November 14, 2019, the Company issued its 3Q19 Press Release that announced, in relevant part:

> …***The FDA was supportive of Neutrolin's proposed manufacturing program***, including the manufacture of the active pharmaceutical ingredients (APIs), the container closure and testing, and indicated that ***it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA filing. No further CMC meetings with the FDA are planned prior to the NDA submission***.

231. Later that day, the Company hosted its 3Q19 Call with investors and analysts at 4:30 ET to discuss, among other things, its 3Q19 financial results. During that call, Defendant Armstrong stated, in relevant part, that:

> As our press release of 16 October indicated ***the outcome of our interaction with the FDA was very positive***. ***FDA was supportive of the core manufacturing processes for the drug product*** and the active pharmaceutical ingredients for the inclusion as part of the NDA submission.
>
> ***FDA did request some additional data which we are working to complete***, so we're optimistic that the CMC module we completed a plan for filing with the FDA. ***FDA did indicate that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA review. No further CMC meetings with FDR are planned prior to the NDA submission***.

232. In addition, Defendant Armstrong stated, in relevant part, during the 3Q19 Call that:

> ***CorMedix has been manufacturing and selling Neutrolin outside the US for the last five years. We've successfully carried out***

> ***technical transfer and validation of the manufacturing process which is enable the successful production of product at three different manufacturing sites.*** As mentioned previously, I have working with me a very experienced and competent team, they have the needed breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance that is necessary for both the US and foreign markets.
>
> During the last earnings call, I covered with you that we are now in the process of finalizing the supply chain and distribution network for the initial product that will be used for launch in the US. ***The initial finished product will be manufactured in Europe.*** Further, we plan to qualify a second third-party manufacturing site in North America. Longer-term, based on our preliminary forecast, we expect to be manufacturing at two or more contract manufacturing site in order to supply the volume of product needed to meet our forecast for the US market. So that background, I would like to make several additional comments with regard to the establishment of the US supply chain. I use the establishment because, CorMedix literally started with nothing in place since we had no sales in the US before.
>
> Hence no establish supply, distribution network in place for the US.
>
> * * *
>
> [T]he drug product manufacturer, that's the vial is in place and ***processes have been established and appropriate validation testing completed to enable manufacture of launch quantities.***

233. The statements referenced in ¶¶230-32 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume

was inconsistent; (ii) Defendants had downplayed the true scope of the FDA's request for more data; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

234. The Company issued its 2/3/20 Press Release, which stated, in relevant part, that "***CorMedix remains on schedule for a potential NDA approval during the second half of 2020***."

235. The statement referenced in ¶234 was materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

236. The Company issued its 3/16/20 Press Release, which announced, in relevant part:

> ***[B]ecause the FDA has announced that it is postponing most foreign inspections through April and inspections outside of the US deemed mission-critical will still be considered on a case-by-case basis, we cannot predict if this will delay approval of the NDA***. Preapproval inspections of the manufacturing facilities relied upon for manufacturing of Neutrolin are required.

237. Defendant Baluch was further quoted in the 3/16/20 Press Release as stating that "[w]e plan to continue our filing schedule and to be on track for a decision in the second half of 2020, although we cannot at this time anticipate the impact on our timetable of the FDA's postponement of most foreign inspections."

238. That same day, CorMedix filed its 2019 10-K with the SEC, signed by Defendants Baluch, Kaplan, Dillione, Dunton, Khan, and Lekfowitz. The 2019 10-K included certain "Risks Related to Dependence on Third Parties" which had already materialized.

239. First, the 2019 10-K warned that "[d]ata provided by collaborators and others upon which we rely that has not been independently verified ***could*** turn out to be false, misleading, or ***incomplete***." Specifically, the 2019 10-K stated that "[w]e rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. ***If such third parties provide*** inaccurate, misleading, or ***incomplete data***, our business, prospects, and results of operations could be materially adversely affected."

240. Second, the 2019 10-K warned that:

> Our contract manufacturers ***may not be able to comply with the applicable FDA regulatory requirements***, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval. They also generally must pass an FDA preapproval inspection for conformity with cGMPs

> before we can obtain approval to manufacture our product candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. ***If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP***, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in a product recall or prevent commercialization of our product candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

241. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendant Baluch certified that "[t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "***[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company***."

242. Later that day, CorMedix hosted its 4Q19 Call with investors and analysts at 4:30 ET to discuss, among other things, its 4Q19 financial results. During that call, Defendant Mounts stated, in relevant part, that:

> FDA announced on March 10th that it is postponing most foreign inspections through April and inspections outside of the US deemed mission critical will still be considered on a case-by-case basis. ***We cannot predict if this will delay approval of the NDA because pre-approval inspections of the manufacturing facilities relied upon for manufacturing of Neutrolin are required***.

243. In addition, during the 4Q19 Call, Defendant Khoso stated, in relevant part, that:

> Our burn rate will increase starting in early 2020 as ***we hired key personnel to prepare for commercialization and commence manufacturing an initial order of Neutrolin for sale upon approval***.
>
> * * *
>
> I'd like to re-emphasize, number one, we are pleased to report to our shareholders that ***the effort to move the regulatory process forward with the FDA is on track***.
>
> * * *
>
> ***The significant experience Phoebe brings in regulatory, Jack in manufacturing and supply chain***, Paul in medical affairs and Liz in clinical operation, ***coupled with my Cialis and Byetta launch experience in the US just to name a few recent launches makes for a winning team***.
>
> ***Together, we have a combined experience of over 170 years in the pharmaceutical business***.

244. The statements referenced in ¶¶236-43 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies,

the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; (iii) the foregoing deficiencies were far more likely to delay approval of the DefenCath NDA than the FDA's postponement of foreign facility inspections; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

245. CorMedix issued its 4/22/20 Press Release, announcing it had completed the sale of $5.5 million of NOL tax benefits through the New Jersey Technology Business Tax Certificate Transfer Program. In that press release, Defendant Baluch was quoted as stating, in relevant part "***[w]e have remained on schedule towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic***."

246. The statement referenced in ¶245 was materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; (iii) the foregoing deficiencies were far more likely to delay approval of the DefenCath NDA than delays at the FDA due to the coronavirus pandemic; and (iv) as a result, the

Company's public statements were materially false and misleading at all relevant times.

247. The 5/11/20 Press Release quoted Defendant Baluch as stating, in relevant part, that "[w]e have been working remotely since mid-March, a transition we have made with little disruption and as a result ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***."

248. That same day, CorMedix filed its 1Q20 10-Q with the SEC which stated that "***[a]s a result of the COVID-19 outbreak, or similar pandemics, and related 'shelter in place' orders and other public health guidance measures, we have and may in the future experience disruptions*** that could materially and adversely impact our clinical trials, business, financial condition and results of operations." Such "[p]otential disruptions" included "***interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems[.]***"

249. The 1Q20 10-Q further stated that:

> ***The extent to which the [COVID-19] outbreak impacts our business***, preclinical studies and clinical trials ***will depend on future developments***, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. ***If we or any of the***

> ***third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.***

250. Appended as exhibits to the 1Q20 10-Q were substantively the same SOX certifications referenced in ¶241, *supra*, signed by Defendant Baluch.

251. Later that day, CorMedix hosted a conference call with investors and analysts at 4:30 ET to discuss, among other things, its 1Q20 financial results ("1Q20 Call"). During that call, in response to a question from analyst Daniel Ferry of LifeSci Advisors about whether the Company "can potentially get approval in the second half of 2020[,]" Defendant Mounts stated, in relevant part, that:

> At this time, ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***. ***We are all very cognizant of preparing an NDA that is complete and provides all of the information in the agency's required format to ensure an efficient review.*** We focused on discussions with FDA in 2019 to make sure that we understood the FDA's expectations to evaluate the manufacturing as well as safety and effectiveness of DEFENCATH. We also believe that by being attentive to the quality and completeness of the submission that we are assisting the FDA to achieve an efficient review process to enable approval in the second half of 2020.

252. In addition, Defendant Baluch stated, in relevant part, later during the 1Q20 Call that "we are extremely pleased that the effort to move the regulatory process forward with the FDA is on track. ***We are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***."

253. The statements referenced in ¶¶247-52 were materially false and

misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA in the second half of 2020; (iii) the foregoing deficiencies were far more likely to delay approval of the DefenCath NDA than any delays at the CMO due to the COVID-19 outbreak; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

254. Pre-market CorMedix issued its 7/8/20 Press Release which stated, in relevant part, that "***all of the modules for the Defencath™ [NDA] have been submitted*** to the [FDA]" and that "***there has been ongoing dialogue with FDA as it reviews the submitted modules***."

255. The 7/8/20 Press Release also quoted Defendant Baluch, who represented, in relevant part, that CorMedix was "very pleased to have ***completed the submission of the NDA***, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission."

256. The statements referenced in ¶¶254-55 were materially false and misleading because Defendants made false and/or misleading statements, as well as

failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the ongoing dialogue with the FDA was reflecting the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

257. CorMedix issued the 8/10/20 Press Release" that represented, *inter alia*, that CorMedix had "***[c]ompleted the rolling submission and review of the [NDA] for Defencath to the FDA*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via catheter."

258. Additionally, the 8/10/20 Press Release quoted Defendant Baluch, who stated, in relevant part, that "[w]e were pleased to announce ***the completion of our rolling submission for Defencath last month*** and look forward to providing updates on the acceptance for filing from FDA" and "[w]e believe ***we have the team***, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

259. That same day, CorMedix filed its 2Q20 10-Q which, in relevant part, discussed its DefenCath NDA submission with the FDA, stating, *inter alia*, that "***[i]n***

March 2020, the Company began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently announced ***on July 8, 2020, that submission of all modules for the NDA was completed***" and that "[t]he Company has not been informed of any delays by the FDA in the review of the NDA[.]"

260. The 2Q20 10-Q also stated that "[a]s a result of the COVID-19 outbreak, or similar pandemics, and related 'shelter in place' orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations." Such "[p]otential disruptions" included "interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems[.]"

261. The 2Q20 10-Q further stated that:

> ***The extent to which the [COVID-19] outbreak impacts our business***, preclinical studies and clinical trials ***will depend on future developments***, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. ***If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.***

262. Appended as exhibits to the 2Q20 10-Q were substantively the same SOX certifications referenced in ¶241, *supra*, signed by Defendants Baluch and David.

263. Later that day, CorMedix hosted its 2Q20 Call with investors and analysts at 4:30 ET to discuss, among other things, the 2Q20 financial results. During that call, Defendant Baluch stated, in relevant part, that:

> I'm very pleased by ***the submission to the FDA of the New Drug Application, or NDA, for DEFENCATH was completed in June***. This submission was completed using the rolling submission format granted by the FDA, ***which we started in March***.
>
> ***Completing this filing was a major undertaking as the team had to work through the Chemistry Manufacturing and Control information, CMC,*** and a large volume of data generated due to the size of LOCK-IT-100 trial and the underlying health issues of the hemodialysis patient group.

264. In addition, during the 2Q20 Call, Defendant Mounts stated, in relevant part, that "***[t]he rolling submission was started in March and completed in June***. Consistent with the rolling submission and review process, ***FDA began an ongoing dialogue with us on the submission as it was in progress***."

265. The statements referenced in ¶¶257-64 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the ongoing dialogue with the FDA was reflecting the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the

process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) the facility manufacturing DefenCath would be installing new equipment about which the CMO and/or CorMedix was failing to provide sufficient information; (iv) in light of the foregoing deficiencies and omissions, the FDA was unlikely to approve the DefenCath NDA; (v) the foregoing deficiencies and omissions were far more likely to delay approval of the DefenCath NDA than any delays at the CMO due to the COVID-19 outbreak; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

266. CorMedix issued its 8/31/20 Press Release announcing the FDA's acceptance for filing and priority review of the DefenCath NDA, setting a PDUFA date of February 28, 2021, for the completion of its review. That press release stated that the FDA "noted that ***it is planning to hold an advisory committee meeting to discuss the [NDA] application*** and that ***it had not identified any potential review issues*** at this time."

267. The 8/31/20 Press Release also quoted Defendant Mounts, who asserted, in relevant part, that "we look forward to ***continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA*** to address an unmet medical need."

268. The statements referenced in ¶¶266-67 were materially false and

misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA's plan to hold an advisory committee meeting reflected the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) the facility manufacturing DefenCath would be installing new equipment about which the CMO and/or CorMedix was failing to provide sufficient information; (iv) in light of the foregoing deficiencies and omissions, the FDA was unlikely to approve the DefenCath NDA; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

269. CorMedix issued its 11/5/20 Press Release, reporting its 3Q20 results and providing a business update. That press release represented, in relevant part, that "***CorMedix continues its interactions with the FDA regarding the ... NDA[] for Defencath™*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via central venous catheter. The FDA has tentatively scheduled the previously announced meeting of the Antimicrobial Drugs Advisory Committee for January 14, 2021 to discuss the Defencath NDA."

270. The 11/5/20 Press Release also quoted Defendant Baluch, who stated, in relevant part, that "[w]e look forward to discussing Defencath with the

Antimicrobial Drugs Advisory Committee in January, ahead of the February 28, 2021 PDUFA date for the product" and that "[w]e believe ***we have the team***, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

271. That same day, CorMedix filed its 3Q20 10-Q which contained substantively the same statements as referenced in ¶259, *supra*, discussing the submission process for the DefenCath NDA while also advising, *inter alia*, that "[t]he FDA noted that it is planning to hold an advisory committee meeting to discuss the application and that ***it had not identified any potential review issues*** at this time[,]" and that "[t]he Company has not been informed of any delays by the FDA in the review of the NDA, but ... ***pre-approval inspections are required for manufacturing sites***."

272. The 3Q20 10-Q also stated that "[a]s a result of the COVID-19 outbreak, or similar pandemics, and related 'shelter in place' orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations." Such "[p]otential disruptions" included "interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems[.]"

273. The 3Q20 10-Q further stated that:

> ***The extent to which the [COVID-19] outbreak impacts our business***, preclinical studies and clinical trials ***will depend on future developments***, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. ***If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.***

274. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications referenced in ¶241, *supra*, signed by Defendants Baluch and David.

275. Later that day, CorMedix hosted a conference call with investors and analysts at 4:30 ET to discuss, among other things, the 3Q20 financial results ("3Q20 Call").[90] During that call, Defendant Baluch reiterated, in relevant part, that the FDA "***is planning to hold an advisory committee meeting to discuss the application and*** that it ***had not identified any potential review issues*** at that time."

276. The statements referenced in ¶¶269-75 were materially false and misleading because Defendants made false and/or misleading statements, as well as

[90] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q3 2020 Results – Earnings Call Transcript*, *SEEKING ALPHA* (Nov. 8, 2020) ("3Q20 Call"), https://seekingalpha.com/article/4386793-cormedix-inc-crmd-ceo-khoso-baluch-on-q3-2020-results-earnings-call-transcript.

failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the continued FDA interactions and the FDA's plan to hold an advisory committee meeting reflected the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those deficiencies; (iii) the facility manufacturing DefenCath would be installing new equipment about which the CMO and/or CorMedix was failing to provide sufficient information; (iv) in light of the foregoing deficiencies and omissions, the FDA was unlikely to approve the DefenCath NDA; (v) the foregoing deficiencies and omissions were far more likely to delay approval of the DefenCath NDA than any delays at the CMO due to the COVID-19 outbreak; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

277. On November 18, 2020, CorMedix issued its 11/18/20 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing the FDA's decision that an advisory committee meeting for the DefenCath NDA was not needed. That press release advised that "CorMedix has been notified that ***based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle***."

278. The 11/18/20 Press Release also quoted Defendant Baluch, who asserted that CorMedix and the FDA were working closely together on the DefenCath NDA, stating that "[w]e are very happy with ***the level of engagement between FDA and the CorMedix team during the NDA review process***."

279. Additionally, the 11/18/20 press Release quoted Defendant Mounts, who likewise asserted that CorMedix and the FDA were working closely together on the DefenCath NDA, stating that "the tremendous effort of the CorMedix team has resulted in ***continuing progress with the FDA in the review of the NDA*** and that the decision was made that ***no discussion with an advisory committee is needed***[,]" and that "[w]e intend to ***continue our effort and dialogue with the [FDA]*** to ensure that the priority review process can be completed expeditiously to address the unmet medical need of hemodialysis patients for an antimicrobial catheter lock solution to prevent life-threatening CRBSI."

280. The statements referenced in ¶¶277-79 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the level of engagement between the FDA and CorMedix reflected the existence of deficiencies at the facility manufacturing DefenCath and/or with respect to the process for withdrawing the labeled volume from the vials such that the fill volume was inconsistent; (ii) the DefenCath NDA reflected those

deficiencies; (iii) the facility manufacturing DefenCath would be installing new equipment about which the CMO and/or CorMedix was failing to provide sufficient information; (iv) in light of the foregoing deficiencies and omissions, the FDA was unlikely to approve the DefenCath NDA; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

C. The Truth Begins to Emerge

281. On March 1, 2021, pre-market, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Receives Complete Response Letter from FDA for DefenCath™ Catheter Lock Solution[,]" "announc[ing] that the [FDA] cannot approve the [NDA] for DefenCath … in its present form." Specifically, CorMedix informed investors that:

> ***FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility. FDA did not specify the issues and CorMedix intends to work with the manufacturing facility to develop a plan for resolution when FDA informs the facility of the specific concerns***. When we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution. Additionally, ***FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials*** despite an existing in-process control to demonstrate fill volume within specifications….Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns. If an inspection is required, the FDA is currently facing a backlog due to the pandemic and are actively working to define an approach for scheduling outstanding inspections once safe travel may

> resume. CorMedix will request a meeting with the FDA, which we estimate will occur by mid-April, to obtain agreement with the Agency on our proposed plan for resolution of the issues at our third-party manufacturing facility.

282. On this news, CorMedix's stock price fell $8.16 per share, or 54.4%, to close at $6.84 per share on March 3, 2021. As *Truist* analyst Lee explained, the CRL "***c[a]me[] as a surprise as the product has already been in production and commercial in the EU, albeit at limited capacity.***" (Emphasis in original).[91]

283. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies at the facility manufacturing DefenCath and with regard to the manufacturing process. As a result, investors were misled into believing that the issues causing the CRL were minor and that the Company would be able to resubmit the DefenCath NDA in the near future.

284. Indeed, after speaking to "the mgmnt team on the CRL" on March 1, 2021, *Truist* analyst Lee of noted that the "40% selloff appears overdone" based on the "lack of fundamental issues with DefenCath itself" in his report titled "Selloff On CMC Issues Overdone. REIT BUY But PT To $30 (-$5) On Launch Delays[.]"[92]

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[91] Joon Lee, M.D., Ph.D., Les Sulewski, *CRL Due To CMC Issues. No Deficiencies Related to Efficacy Or Safety of Defencath*, TRUIST SECURITIES (Mar. 1, 2021).

[92] Joon Lee, M.D., Ph.D., Les Sulewski, *Selloff On CMC Issues Overdone. REIT BUY But PT To $30 (-$5) On Launch Delays*, TRUIST SECURITIES (Mar. 1, 2021).

Mr. Lee also explained, with regards to the "manual extraction study":

> [M]gmnt stated that the vials contain an 'overage' to ensure that labeled volume can be extracted…. It appears to be a routine process and believes a separate study is unlikely to be needed as long as company can convince that FDA that the 'overage' included is sufficient to enable extracting of labeled volume.

285. Then, on March 9, 2021, CorMedix hosted its CRL Call. During that call, Defendant Baluch confirmed that:

> [W]e have received the FDA communication regarding our third-party manufacturing facility and we have been in extensive discussions with the CMO, with the goal of better understanding all of the information submitted to the FDA and the deficiencies identified by the FDA.
>
> We've also been jointly working on draft responses and planned activities to resolve each of the items identified.
>
> ***The time line we outlined from our March 1, 2021, press release for a planned meeting with the FDA of mid-April is still valid based on our current understanding and the progress that we have made to date***.

286. Next, during the CRL Call, Defendant Mounts stated, in relevant part:

> FDA did not approve the new drug application for DEFENCATH and instead issued a complete response letter because it concluded that the manufacturing facility is not ready to support commercial operations for DEFENCATH. This conclusion was based on a review of records requested by FDA from the CMO.
>
> * * *
>
> As I said, there were 6 facility deficiencies remaining at the conclusion of the assessment of the records request. ***Based on our discussions with the CMO, we believe these deficiencies can be resolved in the coming weeks***. For example, ***one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that the equipment is unrelated to the***

> ***manufacturer of DEFENCATH because FDA has requested details to assess the impact to production readiness for DEFENCATH***.
>
> ***Three of the deficiencies involve activities associated with the vial filling line, in particular, the target filling volume. Additionally, a related approvability issue with the FDA's request communicated directly to CorMedix for a required manual extraction study to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials***. As we noted in the March 1 press release, there is an existing in-process control to demonstrate fill volume within specifications. ***We have submitted data to FDA to demonstrate performance with the specifications but we intend to conduct the requested manual extraction study and expect it to be completed in the next several weeks***. Another deficiency identifies concerns an airflow visualization study, and will likely necessitate repeating the study to demonstrate adequate dynamic conditions in the study, which we believe can be accomplished in the next several weeks.
>
> The sixth deficiency requests documentation to support appropriate closing of deviations or nonconformances. ***We are working with the CMO to provide existing documentation to demonstrate that corrective actions are adequate to assure production controls are in place and to ensure standard operating procedures are consistent with actual practices and documentation is completed in a timely manner***.

287. In addition, during the CRL Call, Defendant Armstrong stated, in relevant part:

> Consistent with industry practice, ***we continued to work closely with the CMO via site visits and regular conference calls to prepare for an FDA inspection after submission of the NDA***. We manufactured and validated 3 commercial scale drug product batches. All drug product made at the CMO for validation batches and subsequent batches met specifications. ***The drug product*** was put on accelerated and normal stability testing and ***continues to meet specifications.***

288. Defendant Baluch further added during the CRL Call, in relevant part, that "[w]e are working as fast as we can, in concert with the CMO, which is fully

cooperating to develop and execute the plan. We believe ***we have within CorMedix and the CMO, the resources and capabilities to achieve successful resolution of the manufacturing deficiencies to the satisfaction of the FDA***."

289. Later during the CRL Call, *JMP* analyst Jason Nicholas Butler asked for "more color you can give on FDA's issues with the vial finishing lines? Anything you can tell us about whether these lines are used solely for DEFENCATH or other products? Or anything that's unique or different about these lines versus other fill/finish facilities? And then, just in terms of your overfill margins, is there anything you're doing different here? Or anything different to industry standard in terms of your overfill margins?" In response, Defendants Mounts and Armstrong stated, in relevant part:

- Mounts: "I can confirm that ***the fill lines are solely for DEFENCATH***. ***So they're not used for any other product manufacture***. As you can imagine, a lot of the information involved in filling lines is proprietary to the facility. And as you will likely expect, there is a confidentiality agreement in place to protect that information. So I cannot disclose any more specific information about the vial filling line."

- Armstrong: "We are following the guidelines that are given, and we are following the guidelines on the overfill. And it's not different than we were doing before. We are within the guidelines."

290. Further, in response to Daniel Ferry of *LifeSci Advisors, LLC* asking "[h]ow can you say that CorMedix was not informed by the FDA of manufacturing facility deficiencies[,]" Defendant Baluch stated, in relevant part, that: "I can assure you that despite whatever assertions there is in the public domain, ***CorMedix was***

not informed by the FDA of the deficiencies. Inspection observations are commonly shared with the facility directly, and FDA referred us to contact the manufacturing facility for the information to maintain appropriate confidentiality of the facilities information, and that's pretty standard."

291. The statements referenced in ¶¶285-90 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) Defendants knew or should have known about the deficiencies in the process for withdrawing the labeled volume from the vials since before the Class Period when the Company was having CMC discussions with the FDA; (ii) the manual extraction study conducted by CorMedix and its CMO would not be sufficient to demonstrate that the labeled volume could be consistently withdrawn from the vials; (iii) Defendants knew or should have known about the new equipment being installed at the facility for another drug product since at least the CMO's July 2020 public announcement; (iv) since the CMO manufactured multiple different drug products, Defendants should have ensured that the CMO's protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards; (v) deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and would cause contaminated vials, which would delay the CMO's ability to obtain the data

requested by the FDA relating to the qualification of the filling operation; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

292. Then, on March 30, 2021, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its 4Q20 results and providing a business update.[93] That press release continued to generally advise that the "***FDA noted concerns at the third-party manufacturing facility*** after a review of records requested by FDA and provided by the manufacturing facility, and has requested ***a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from vials***" and "CorMedix continues to work closely with our third-party manufacturing facility and is planning for a meeting with the FDA in mid-April to obtain agreement on the adequacy of our proposed plans for resolution of the deficiencies."

293. That same day, CorMedix filed an annual report on Form 10-K with the SEC, reporting its financial and operating results for the quarter and year ended December 31, 2020[94] ("2020 10-K"). The 2020 10-K advised, *inter alia*:

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[93] *CorMedix Inc. Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update*, GLOBENEWSWIRE (March 30, 2021, 16:05 ET) ("3/30/21 Press Release"), https://www.globenewswire.com/news-release/2021/03/30/2201949/0/en/CorMedix-Inc-Reports-Fourth-Quarter-and-Full-Year-2020-Financial-Results-and-Provides-Business-Update.html.

[94] CorMedix, Inc., Annual Report (Form 10-K) (Mar. 30, 2021).

> As we announced in March 2021, the FDA has informed us that it will not approve the NDA for DefenCath in its present form. ***The FDA noted concerns at the third-party manufacturing facility*** after a review of records requested by the FDA and provided by the manufacturing facility. We are working with the manufacturing facility to develop plans for resolution of the deficiencies. Additionally, ***the FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications***. ***We expect to be able to complete this requirement expeditiously.*** Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns.

294. With respect to CorMedix's CMOs, the 2020 10-K assured investors, in relevant part, that Defendants "are confident that [our] ***CMO's [for DefenCath] have adequate capacity to produce the volumes needed***, [and] that there exists a sufficient number of potential alternate sources for the drug substances required to produce our products, as well as third-party manufacturers[.]"

295. Appended as exhibits to the 2020 10-K were substantively the same SOX certifications referenced in ¶241, *supra*, signed by Defendants Baluch and David.

296. Later that same day, Defendants hosted the Company's 4Q20 Call at 4:30ET to discuss, among other things, its 4Q20 financial results. During that call, Defendant Baluch assured investors that "we remain confident that ***we have the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified."

297. In addition, during the 4Q20 call, Defendant Mounts advised:

> I will start with the all-important timeline. The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains on track based on the progress we have made. We have been working intensely with our third-party manufacturing facility to develop the proposed resolutions to the deficiencies.
>
> There has been a strong collaborative effort to develop responses for each of the six deficiencies identified by FDA for the manufacturing facility. In addition, ***we have developed the protocol for the manual extraction study being required by FDA to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials***.
>
> I am pleased to announce that FDA has granted our request to meet with them to begin resolving the outstanding deficiencies. As we have previously stated, the purpose of the meeting with FDA is to obtain agreement with the agency on the adequacy of our proposed plans for resolution of the deficiencies. Our contract manufacturing organization will join us in the meeting with FDA.
>
> As we planned, the meeting will occur in mid-April, and we will provide an update on our progress and timeline for resolution of the deficiencies after the meeting with FDA. Our goal is to ensure that FDA can conclude that the manufacturing facility is ready to support commercial operation for DEFENCATH without the need for an on-site inspection.
>
> As I have explained on previous calls, FDA identified the deficiencies based on a review of records that it had requested from the CMO.

298. On the same call, regarding CorMedix's anticipated meeting with the FDA to discuss the DefenCath NDA, *JMP* analyst Jason Butler asked whether "you will actually have any of the work requested by FDA completed by the meeting, either in terms of documentation protocols, or the vial fill volume study or airflow

visualization studies that they asked for," and whether "you've actually completed any, or have any new data to take to the meeting?" In response, Defendant Mounts assured investors, "yes, we obviously were involved in developing the proposed responses"; that "[s]ome of those proposed responses involve existing documentation"; that "***we make sure that we -- where we could, we provided information that was responsive to the deficiency***"; and that "***there is new information there for them to review for some of the responses***."

299. The *JMP* analyst followed up by noting "[y]ou mentioned that there was a couple of questions related to equipment that was not relevant to DEFENCATH" and asked "[i]s it still your view that those parts of the CRL are for equipment not relevant to DEFENCATH?" In response, Defendant Mounts stated:

> Maybe, yes. Yes, Jason***, the issue was planned expansion at the manufacturing facility, which involved installation of new equipment. That is new equipment non-intended for manufacturer of DEFENCATH. So, the information that has been used and is in place is the appropriate equipment for DEFENCATH manufacture***.

300. On the same call, a *Truist* analyst observed: "[T]he impression is that it was the [CMO's] deficiencies, so what are you -- why do you need to be involved in addressing their issues? What is it that you can contribute to the CMO's deficiencies?" In response, Defendant Mounts advised:

> I think folks don't understand that there's a parallel process here. As you noted, we have direct control over documentation and information on manufacturing, that's submitted directly to the new drug application. As part of that process, FDA inspects the manufacturing

> facility and reviews documentation and the facility for its ability to manufacture that product in a commercial setting.
>
> So the inspection by FDA, whether it's by records assessment or an on- site inspection, involves reviewing manufacturing records for the product in the NDA, but ***it also goes broader than that. It goes to the actual facility and the equipment to the maintenance and the training and the personnel.***
>
> So, it's a parallel process, but ***obviously they are intertwined and can't be separated, because FDA is there to look at the potential for that facility to manufacture the product that's the subject of the NDA.***

301. The statements referenced in ¶¶292-300 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the manual extraction study conducted by CorMedix and its CMO would not be sufficient to demonstrate that the labeled volume could be consistently withdrawn from the vials; (ii) since the CMO manufactured multiple different drug products, Defendants should have ensured that the CMO's protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards; (iii) deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and would cause contaminated vials, which would delay the CMO's ability to obtain the data requested by the FDA relating to the qualification of the filling operation; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

302. On April 14, 2021, pre-market, CorMedix issued its 4/14/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing "that it has met with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [CRL] to CorMedix and the Post-Application Action Letter received by the third-party manufacturer (CMO) from FDA for the [NDA] for DefenCath." Specifically, that press release disclosed that CorMedix would have to take additional steps to meet the FDA's requirements for DefenCath's manufacturing process, stating, in relevant part:

> Addressing FDA's concerns regarding the qualification of the filling operation may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath. CorMedix and the CMO are currently evaluating available data to determine if additional process qualification will be needed with subsequent validation to address these issues.
>
> The FDA stated that the review timeline would be determined when the NDA resubmission is received and that it expected all corrections to facility deficiencies to be complete at the time of resubmission so that all corrective actions may be verified during an on-site evaluation in the next review cycle, if the FDA determines it will do an onsite evaluation.

303. On this news, CorMedix's stock price fell $1.72 per share, or 18.36%, to close at $7.65 per share on April 15, 2021. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies at the

facility manufacturing DefenCath and with regard to the manufacturing process.

304. First, assuring investors that "[r]epresentatives from both CorMedix and the CMO participated in the meeting with FDA to ensure that there is alignment on addressing the [FDA]'s concerns[,]" the April 2021 Press Release stated, in relevant part, that "[t]here is now an agreed upon protocol for the manual extraction study identified in the CRL that ***FDA is requiring as confirmation of in-process controls to demonstrate that the labeled volume can be consistently withdrawn from the vials***[,]" "CorMedix expects to be able to ***complete this requirement in the next several weeks***[,]" "***CorMedix and the CMO continue to work closely*** to ensure that the identified deficiencies are resolved prior to resubmission of the Defencath NDA[,]" and "***CorMedix will provide updates on the timeline as resolution of the deficiencies proceeds***."

305. Next, CorMedix's April 14, 2021 Corporate Presentation stated, in relevant part, regarding DefenCath's "Regulatory Status":

- Received a [CRL] from FDA that indicated the need to: (1) resolve deficiencies at third-party manufacturing facility, where a pre-approval inspection could not be conducted due to the pandemic and (2) conduct a manual extraction study to confirm volume in DefenCath vials
- Draft labeling for Limited Population of patients with kidney failure receiving hemodialysis via CVC pursuant to LPAD.
- Met with FDA to align on proposed manual extraction study and discuss

resolution of deficiencies identified at third-party manufacturing facility.[95]

306. In addition, the April 2021 Presentation stated, in relevant part, when providing a "Manufacturing Overview: Supply Chain Substantially Completed; Launch Quantities in Production" that CorMedix had "***[s]uccessfully concluded technical transfer and validation of the drug product manufacturing process***, which has enabled production at 2 different manufacturing locations[,]" and that "***[l]aunch quantities are already in production***[.]"

307. The statements referenced in ¶¶304-06 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) since the Company's CMO manufactured multiple different drug products, Defendants should have ensured that the CMO's protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards; (ii) deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and would cause contaminated vials, which would delay the CMO's ability to obtain the data requested by the FDA demonstrating that the labeled volume could be consistently withdrawn from the vials; and (iii) as a result, the Company's public statements were materially false and

[95] *Corporate Presentation*, CORMEDIX, INC. (Apr. 14, 2021) ("April 2021 Presentation") https://www.cormedix.com/wp-content/uploads/2021/04/CorMedix_Corporate-Presentation_4-14-21-v3.pdf.

misleading at all relevant times.

308. On May 13, 2021, post-market, CorMedix issued its 5/13/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its results for the first quarter of 2021 ("1Q21") and providing a business update. That press release disclosed, in relevant part, that "[b]ased on our analyses, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA."

309. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2021[96] (the "1Q21 10-Q"). The 1Q21 10-Q contained substantively the same statements as referenced in ¶293, *supra*, discussing the submission process for the DefenCath NDA while also disclosing, *inter alia*, that "[a]ddressing the FDA's concerns regarding the qualification of the filling operation may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath" and that "[t]he Company and the CMO are currently evaluating available data to determine if additional process qualification will be needed with subsequent validation to address these issues."

310. Later that same day, also post-market, Defendants hosted a conference call with investors and analysts to discuss, among other things, CorMedix's progress

[96] CorMedix, Inc., Quarterly Report (Form 10-Q) (May 13, 2021).

with the DefenCath NDA.[97] On that call, Defendant Baluch stated in his opening remarks, in relevant part, that "addressing FDA's concern regarding the qualification of the filling operation at the third-party manufacturing facility may necessitate adjustments in the process and generation of additional data on operating parameters for the manufacturing of DEFENCATH."

311. Defendant Mounts further detailed in her opening remarks during the 1Q21 Call, in relevant part, that:

> As we have explained previously, the major focus of FDA's concerns was on the qualification of the filling operation and CorMedix and the CMO have been evaluating available data to assess the need for adjustments in the manufacturing process and generation of additional data on operating parameters for manufacture of DEFENCATH.
>
> Based on our analysis, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA. As a result, ***our current plan is to be able to resubmit the [DEFENCATH] NDA in the fourth quarter of 2021***.

312. Dissatisfied with Defendants continued ambiguous and general descriptions of the deficiencies identified with DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath, Needham analyst

[97] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q1 2021 Results - Earnings Call Transcript*, SEEKING ALPHA (May 13, 2021, 04:30 PM ET) ("1Q21 Call"), https://seekingalpha.com/article/4428474-cormedix-inc-crmd-ceo-khoso-baluch-on-q1-2021-results-earnings-call-transcript.

Chad Messer pressed Defendants for clearer details on the deficiencies and the Company's steps to address them, stating, in relevant part:

> When you say you have additional qualification processes that need to address the FDA, and you think you can submit in the fourth quarter an NDA. And then later on, you were talking about some manufacturing, validation that you need beforehand as much as you can. And I get it. These are not easy questions, and there is a lot of uncertainties to deal with the FDA. But can you maybe timeline me through or just slowly, treat me like I'm not all that smart…. What the steps are that you think you need to achieve by this 4Q NDA submission?

313. Specifically pressed for more details and a clearer picture of the regulatory hurdles currently facing CorMedix's manufacturing for DefenCath, Defendant Mounts disclosed, in relevant part:

> [I]t is a complicated process and that it is not simple, and like all technical work, needs to be conducted with precision and is subject to issues when something can go wrong. It is highly sophisticated equipment. And so there are times when there may be unexpected results obtained.
>
> FDA's concern as they express to us during our meetings with them focused on the filling operation, which is the process by which DEFENCATH is during a sterile procedure loaded into the vials and then the vials are kept.
>
> They expect us to generate sufficient data to demonstrate that, that process is a controlled process and is consistent with the agency's requirements for good manufacturing practice. So clearly, sterility is a very important part of that process, but also the accuracy in making sure the right volume of DEFENCATH is loaded into the vials. And we are talking about thousands of vials during the manufacturing run.
>
> So as I said, it is a complicated process and technically very involved and involves a generation of a lot of data to make sure that the process itself is using the jargon qualified, which means all the

> equipment has been qualified for the intended use and every step in the manufacturing process has been qualified.
>
> And that everything works as it is intended to produce the product that has to meet its specifications**.** So they are very detailed requirements on a chemical basis as well on a performance basis that is required for the product.
>
> And so that process needs to be very robust, needs to be reproducible. And the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution.

314. Then, *JMP* analyst Jason Butler asked "the additional in process qualification work, have you already agreed with your CMO what the plan is there? And what needs to be done? And is there any granularity you can give us in terms of time lines to complete that work?" In response, Defendant Mounts stated:

> Yes, ***we have agreed with the CMO on the plan to go forward to resolve the deficiencies and generate the additional data required by FDA.*** As we have said, the FDA has focused on the in-process controls and has requested some additional data on the process qualification. And as a result of that, we will be required to manufacture the validation batches to fulfill the request from the agency.

315. On this news, CorMedix's stock price fell $1.51 per share, or 19.97%, to close at $6.05 per share on May 14, 2021. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies at the facility manufacturing DefenCath and with regard to the manufacturing process.

316. For example, the 5/13/21 Press Release stated, in relevant part, that

"***CorMedix successfully completed the agreed upon protocol for the manual extraction study identified in the Complete Response Letter*** that FDA is requiring as confirmation of in-process controls to demonstrate that the labeled volume can be consistently withdrawn from the vials.

317. In addition, Defendant Baluch is quoted in the 5/13/21 Press Release as stating, in relevant part, "As we continue to work through the items required by FDA for resubmission of the NDA, we remain confident in our efforts[,]" and "[w]e believe ***we have the right team and resources to accomplish this as we advance DefenCath through the regulatory approval process***."

318. Further, the 1Q21 10-Q assured investors that "***[t]he Company and the CMO continue to work closely to ensure that the identified deficiencies are resolved*** prior to resubmission of the DefenCath NDA."

319. Appended as exhibits to the 1Q21 10-Q were substantively the same SOX certifications referenced in ¶241, *supra*, signed by Defendants Baluch and David.

320. Next, during the 1Q21 Call, Defendant Baluch stated, in relevant part, that "[w]e remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency***."

321. The statements referenced in ¶316-20 were materially false and misleading because Defendants made false and/or misleading statements, as well as

failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) since the Company's CMO manufactured multiple different drug products, Defendants should have ensured that the CMO's protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards; (ii) deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and would cause contaminated vials, which would delay the CMO's ability to obtain the data requested by the FDA demonstrating that the labeled volume could be consistently withdrawn from the vials; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

322. Then, on August 12, 2021, CorMedix issued its 8/12/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its 2Q21 results and providing a business update. That press release stated, in relevant part, that "CorMedix remains focused in its efforts to resolve the deficiencies sent to the third-party manufacturer in the Post-Application Action Letter and ***remains on schedule to re-submit the DefenCath™ New Drug Application in the fourth quarter of 2021***."

323. Later that day, Defendants hosted the Company's 2Q21 Call with investors and analysts at 4:30 ET to discuss, among other things, its progress with the DefenCath NDA. On that call, Defendant Baluch stated, in relevant part, during

his opening remarks:

> During the last earnings call on May 13, we provided an update on the progress that CorMedix has made to date on addressing the deficiencies identified by the FDA as the third-party manufacturing facility. The work has continued and we are reiterating that ***at present, we are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021.***
>
> **** * ****
>
> We remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified*** and bring DEFENCATH to hemodialysis patients in the U.S.

324. In addition, Defendant Mounts stated, in relevant part, that:

> I will start by assuring you that ***we remain on schedule to resubmit the new drug application or NDA in the fourth quarter of 2021***.
>
> * * *
>
> [A]s we have explained previously, resolution of the deficiencies at the manufacturing facility identified in the post-application action letter sent to the CMO has required additional process qualification with subsequent validations for the vial filling process. The process qualification and validation are done by the manufacturing facility and ***we are working closely with them and CMC consultants engaged by CorMedix to ensure that we are addressing FDA concerns appropriately***.
>
> The deficiencies communicated to the CMO by FDA need to be satisfactorily addressed for approval of the DEFENCATH NDA. ***The CMC and regulatory teams of CorMedix are working collaboratively with the CMO to ensure the generation of the required data and documentation to resubmit the NDA in the fourth quarter of 2021***.

325. During the Q&A Session of the 2Q21 Call, *Truist* analyst Lee "[r]egarding the process qualification of vials and the vial filling process, and the

manual extraction studies. Did those require production of new batches of DEFENCATH? And if so, will you need stability data from those new batches before you can submit the NDA or during the process of NDA [Indiscernible]?" In response, Defendant Mounts stated:

> [A]s I've explained, we need to do some, as you said, process qualification. And then you need to validate that by generating additional batches and part of the program for any manufactured batches that are intended for commercial use, or to put those batches into a stability program, and to generate stability data to demonstrate in fact that the product is stable and continues to meet specifications.
>
> ***We have an abundance of data on stability of other batches that have been produced. And so we expect to be able to show consistency.***

326. Then, analyst Chad Messer of Needham asked "[i]s it possible for you to give us a little bit of sort of historical perspective on what kind of issues we may or may not have to have to deal with inspection like that?" In response, Defendant Mounts stated, in relevant part:

> There's an abundance of information in FDA database from warning letters, where FDA has gotten and inspected manufacturing facilities. So ***it's obvious the kinds of things that the agency looks for when it does an inspection.*** So that certainly can provide you with this historical perspective.

327. The statements referenced in ¶¶322-26 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) since the Company's CMO manufactured multiple different drug products, Defendants should have ensured that the CMO's protocols relating to

changeover of manufacturing lines and visual inspections of drug products met cGMP standards; (ii) deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and did cause contaminated vials in July 2021, which would delay the CMO's ability to obtain the data requested by the FDA demonstrating that the labeled volume could be consistently withdrawn from the vials; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

D. The Truth Fully Emerges

328. Finally, before markets opened on September 7, 2021, the Company issued its 9/7/21 Press Release, disclosing that "CorMedix has encountered delays at its third-party [CMO]" relating to "issues that are unrelated to DefenCath manufacturing activities" and that "the timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA is uncertain at this time."

329. On this news, CorMedix's stock price fell $1.77 per share, or 27.40%, to close at $4.69 per share on September 9, 2021.

330. As SA News Editor Mamta Mayani noted on September 7, 2021, CorMedix's stock price "slump[ed] 20.6% premarket after the company provided an update with respect to its resubmission timeline for the DefenCath [NDA]."

331. Likewise, a September 7, 2021 article by the Motley Fool titled "Why

CorMedix Stock Is Getting Crushed Today" noted that the Company's "stock was getting crushed on Tuesday, with shares down 23.7% as of 11 a.m. EDT … after the company announced that it 'has encountered delays at its third-party contract manufacturer.' These delays will push back CorMedix's refiling for [FDA] approval of its DefenCath antibacterial and antifungal catheter lock solution by an undetermined amount of time."

332. These delays in CorMedix's NDA resubmission also indicated the Company did not have the "right team" to resolve the CMO's deficiencies, as confirmed on October 4, 2021.[98] That day, just a month after the resubmission delays were announced, CorMedix disclosed changes to its executive leadership team, effective immediately, including Defendant Baluch retiring from his role as CEO and resigning from the Company's Board (after being "at the helm" for over five years), and Defendant Armstrong retiring from CorMedix with Defendant Mounts taking over the Company's "technical operations group, including a group of consultants that are working on addressing the situation with the CMO."[99]

[98] *Cormedix Inc. Announces Executive Leadership Changes*, CORMEDIX, INC. (Oct. 4, 2021) https://www.cormedix.com/cormedix-inc-announces-executive-leadership-changes/.

[99] Joseph Sullivan, *A month after a manufacturing hiccup led to a CRL, CorMedix CEO will retire*, ENDPOINTS NEWS (Oct. 5, 2021, 07:20 AM EDT) https://endpts.com/a-month-after-a-manufacturing-hiccup-led-to-a-crl-cormedix-ceo-will-retire/.

333. Then, on November 9, 2021, Defendants confirmed once again that CorMedix did not have the "right team" at CorMedix or the CMO to resolve the deficiencies identified by the FDA. During the Q&A portion of the Company's 3Q21 Earnings Call, in response to a pre-submitted written question, which recalled that "CorMedix referred to specialized consultants in a recent press release[,]" and asked Defendants to "elaborate on this and discuss how they are assisting the company with the resubmission process[,]" Defendant Mounts stated, in relevant part:

> Obviously, we have CorMedix specialists, but because of the importance of these activities and the need to have everything done as quickly as possible, we have engaged the team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection.
>
> So, we wanted to make sure that we had adequate resources and sufficient knowledge of what FDA will be looking for to make sure that we were being comprehensive and complete in all of our activities.

334. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

E. Loss Causation

335. The false and misleading misrepresentations and material omissions, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class members he represents.

336. During the Class Period, as detailed herein, Plaintiff and the 1934 Act

Class members purchased CorMedix securities at artificially inflated prices and were damaged thereby. The price of the Company's securities declined significantly when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were disseminated and publicly revealed.

337. During the Class Period, the CorMedix Defendants materially misled the investing public, thereby inflating the price of CorMedix securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make the statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about CorMedix's business, operations, and prospects, as alleged herein.

338. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the 1934 Act Class. The CorMedix Defendants made or caused to be made materially false and/or misleading statements about CorMedix's business, operations and future prospects. These material misstatements and/or omissions had the cause and effect of creating in the market a false positive assessment of the Company and its business and operational performance and related well-being, thus causing its

securities to be overvalued and the price of its securities to be artificially inflated at all relevant times. Defendants' materially false and/or misleading statements, as alleged herein, resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was partially revealed March 1, 2021, April 14, 2021, and May 13, 2021, and then fully on September 7, 2021, causing the trading price of CorMedix securities to materially decline and removing the previously embedded artificial inflation.

F. Applicability of the Presumption of Reliance: Fraud-on-the-Market Doctrine

339. Plaintiff and the other members of the 1934 Act Class will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things: (a) the CorMedix Defendants made public misrepresentations or failed to disclose material facts; (b) the omissions and misrepresentations were material; (c) the Company's securities traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and (e) Plaintiff and the other members of the 1934 Act Class purchased CorMedix securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

340. At all relevant times, the market for CorMedix securities was efficient

for the following reasons, among others: (a) CorMedix securities met the listing requirements for, and were listed and actively traded on the NASDAQ and the NYSE, highly efficient markets; (b) during the Class Period, CorMedix shares were actively traded, supporting a strong presumption of efficiency; (c) CorMedix issued public reports with the SEC; (d) CorMedix regularly communicated with public investors, including via regular disseminations of press releases on major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; (e) CorMedix was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force, certain customers of their respective brokerage firms, and were publicly available; and (f) unexpected material news about CorMedix was rapidly reflected in and incorporated into the price of its securities during the Class Period.

341. Because CorMedix is a publicly traded company, the CorMedix Defendants knew, understood and had reason to expect that: (1) their misstatements would artificially inflate the price of CorMedix securities; (2) investors would rely on the price of CorMedix common stock as reflecting accurate information known to CorMedix and its executives; and (3) their misstatements and omissions would induce Plaintiff and the other members of the 1934 Act Class to purchase CorMedix securities during the Class Period.

342. As a result of the foregoing, the market for CorMedix's securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in CorMedix's share price. Under these circumstances, all purchasers of CorMedix's securities during the Class Period suffered similar injury through their purchase of CorMedix's securities at artificially inflated prices and a presumption of reliance applies.

343. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on the CorMedix Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding CorMedix's business, operations, and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

G. No Safe Harbor

344. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged in

this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

345. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of CorMedix who knew that the statement was false and/or misleading when made.

H. Class Action Allegations by the 1934 Act Class

346. Plaintiff brings this action as a class action pursuant to Rules 23(a) and (b)(3) on behalf of all persons and entities who purchased or otherwise acquired CorMedix securities between October 16, 2019 and September 6, 2021, inclusive (the "Class Period"). This class of investors asserts claims only for violations of Sections 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.1 b-5 (the "1934 Act

Class"). Excluded from the 1934 Act Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

347. The members of the 1934 Act Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, CorMedix securities were actively traded on the NASDAQ and NYSE. While the exact number of 1934 Act Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed 1934 Act Class. Record owners and other members of the Class may be identified from records maintained by CorMedix or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

348. Plaintiff's claims are typical of the claims of the 1934 Act Class members as all members of the 1934 Act Class are similarly affected by Defendants' wrongful conduct, in violation of federal securities law, complained of herein.

349. Plaintiff will fairly and adequately protect the interests of the members of the 1934 Act Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the 1934 Act Class.

350. Common questions of law and fact exist as to all members of the 1934 Act Class and predominate over any questions solely affecting individual members. Among the questions of law and fact common to the 1934 Act Class are:

- whether federal securities laws were violated by the CorMedix Defendants' acts as alleged herein;
- whether statements made by the CorMedix Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of the Company;
- whether the Officer Defendants caused CorMedix to issue false and misleading financial statements during the Class Period;
- whether the CorMedix Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of the Company's securities during the Class Period were artificially inflated because of the CorMedix Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

351. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the 1934 Act Class may be relatively small, the expense and burden of individual litigation makes it impossible for them to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I
Violations of § 10(b) of the 1934 Act and Rule 10b-5
(Against the CorMedix Defendants)

352. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

353. This Count is asserted against Defendants and is based upon § 10(b) of the 1934 Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder.

354. During the Class Period, the CorMedix Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the 1934 Act Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other 1934 Act Class members, as alleged herein; (ii) artificially inflate and maintain the market price of CorMedix securities; and (iii) cause Plaintiff and other members of the 1934 Act Class to purchase or otherwise acquire CorMedix securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the CorMedix

Defendants took the actions set forth herein.

355. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the CorMedix Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for CorMedix securities. Such reports, filings, press releases and other statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about CorMedix's finances and business prospects.

356. By virtue of their positions at CorMedix, the Officer Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the 1934 Act Class, or, in the alternative, the Officer Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Officer Defendants.

357. Said acts and omissions of the CorMedix Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the CorMedix

Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

358. Information showing that the CorMedix Defendants acted knowingly or with reckless disregard for the truth is peculiarly within their knowledge and control. As the senior managers and/or directors of CorMedix, the Officer Defendants had knowledge of the details of CorMedix's internal affairs.

359. The Officer Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Officer Defendants were able to and did, directly or indirectly, control the content of the statements of CorMedix. As officers and/or directors of a publicly held company, the Officer Defendants had a duty to disseminate timely, accurate, and truthful information with respect to CorMedix's business, operations, prospects, and future financial condition.

360. As a result of the dissemination of the false and misleading reports, releases and public statements described herein, the market price of CorMedix securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning CorMedix's business and financial condition which were concealed by the CorMedix Defendants, Plaintiff and the other members of the 1934 Act Class purchased or otherwise acquired CorMedix securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market

for the securities, and/or upon statements disseminated by Defendants, and were damaged thereby.

361. Had Plaintiff and the other members of the 1934 Act Class known the truth, they would not have purchased or otherwise acquired them at the inflated prices that were paid, or at all. At the time of the purchases and/or acquisitions by Plaintiff and the 1934 Act Class, the true value of CorMedix securities was substantially lower than the prices paid. The market price of CorMedix securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and the 1934 Act Class members.

362. By reason of the conduct alleged herein, Defendants, knowingly or recklessly, directly, or indirectly, violated § 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder.

363. As a direct and proximate result of the CorMedix Defendants' wrongful conduct, Plaintiff and the other members of the 1934 Act Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Violations of § 20(a) of the 1934 Act
(Against the Officer Defendants)

364. Plaintiff repeats and re-alleges each and every allegation contained in

the foregoing paragraphs as if fully set forth herein.

365. During the Class Period, the Officer Defendants participated in the operation and management of CorMedix, and conducted and participated, directly and indirectly, in the conduct of CorMedix's business affairs. Because of their senior positions, they knew the adverse non-public information about CorMedix's misstatement of income and expenses and false financial statements. As officers and/or directors of a publicly owned company, the Officer Defendants had a duty to disseminate accurate and truthful information with respect to CorMedix's financial condition and results of operations, and to correct promptly any public statements issued by CorMedix which had become materially false or misleading.

366. Because of their positions of control and authority as senior officers, the Officer Defendants were able to, and did, control the contents of the various reports, press releases and public filings which CorMedix disseminated in the marketplace during the Class Period concerning its results of operations. Throughout the Class Period, the Officer Defendants exercised their power and authority to cause CorMedix to engage in the wrongful acts complained of herein. The Officer Defendants, therefore, were "controlling persons" of CorMedix within the meaning of § 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of CorMedix securities.

367. Each of the Officer Defendants, therefore, acted as a controlling

person of CorMedix. By reason of their senior management positions and/or being directors of CorMedix, each of the Officer Defendants had the power to direct the actions of, and exercised the same to cause, CorMedix to engage in the unlawful acts and conduct complained of herein. Each of the Officer Defendants exercised control over the general operations of CorMedix and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

368. By reason of the above conduct, the Officer Defendants are liable pursuant to § 20(a) of the Exchange Act for the violations committed by CorMedix.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other member of the Classes, prays for relief and judgment against as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23, and certifying Plaintiff as the Class representative;

B. Awarding compensatory damages in favor of Plaintiff and the other members of the Classes against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Classes their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding Plaintiff and other members of the Classes such other and further relief as this Court may deem just and proper.

VII. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: December 14, 2021

Respectfully Submitted,

ROCHE FREEDMAN LLP

/s/ Ivy T. Ngo
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
Constantine P. Economides (*pro hac vice* forthcoming)
1 SE 3rd Ave., Suite 1250
Miami, Florida 33131
Telephone: (305) 971-5943
ingo@rochefreedman.com
vel@rochefreedman.com
ceconomides@rochefreedman.com

POMERANTZ LLP
Josh Silverman (*pro hac vice*)
Louis C. Ludwig
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jpsilverman@pomlaw.com
lcludwig@pomlaw.com

Thomas H. Przybylowski
600 Third Avenue
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
tprzybylowski@pomlaw.com

Counsel for Lead Plaintiff and the Class

THE SCHALL LAW FIRM
Brian Schall (*pro hac vice* forthcoming)
1880 Century Park East, Suite 404
Los Angeles, CA 90067
Telephone: (424) 303-1964
brian@schallfirm.com

Additional Counsel for Lead Plaintiff

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff, by his attorneys, hereby certifies that to the best of his knowledge, the matter in controversy is not related to any other action. Plaintiff is not currently aware of any other party who should be joined in this action.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: December 14, 2021

Respectfully Submitted,

ROCHE FREEDMAN LLP
/s/ Ivy T. Ngo
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
Constantine P. Economides (*pro hac vice* forthcoming)
1 SE 3rd Ave., Suite 1250
Miami, Florida 33131
Telephone: (305) 971-5943
ingo@rochefreedman.com
vel@rochefreedman.com
ceconomides@rochefreedman.com

POMERANTZ LLP
Josh Silverman
Louis C. Ludwig
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jpsilverman@pomlaw.com
lcludwig@pomlaw.com

Thomas H. Przybylowski
600 Third Avenue

New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
tprzybylowski@pomlaw.com

Counsel for Lead Plaintiff and the Class

THE SCHALL LAW FIRM
Brian Schall (*pro hac vice* forthcoming)
1880 Century Park East, Suite 404
Los Angeles, CA 90067
Telephone: (424) 303-1964
brian@schallfirm.com

Additional Counsel for Lead Plaintiff